

US3832074 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:03:19

All time stamps listed in this document are displayed in GMT

US3832074

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

[Participant ID](#)

US3832074

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

US3832074

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Date of Birth (MMM yyyy)	(b) (6) 1938
Age	82
Age Units	YEARS
Age (Derived)	82
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3832074

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:45
Height (xxx.x)	167.6 cm
Weight (xxx.x)	82.1 kg
BMI (xxx.x)	29.22773 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Date of assessment (dd MMM yyyy) 04 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1970

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:25

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:25

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

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

What was the participant's randomization number? 184591

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:45
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 12:56
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 12:26 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 12:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	12:11 (24 HR)
Collection date and time (derived)	04 AUG 2020 12:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:10	04 AUG 2020 12:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 13:00

PC Open Date & Time

04 AUG 2020 12:46

PC Close Date & Time

04 AUG 2020 15:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 19:00

PC Open Date & Time

04 AUG 2020 16:11

PC Close Date & Time

05 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

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

05 AUG 2020 19:06

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

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

97.6 °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

06 AUG 2020 18:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

08 AUG 2020 20:15

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 18:36

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 13:01

PC Open Date & Time

04 AUG 2020 12:46

PC Close Date & Time

04 AUG 2020 15:16

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 19:01

PC Open Date & Time

04 AUG 2020 16:11

PC Close Date & Time

05 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 19:08

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 18:29

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 20:16

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 18:37

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

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

10 AUG 2020 18:48

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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 ☐

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 13:03
PC Open Date & Time	04 AUG 2020 12:46
PC Close Date & Time	04 AUG 2020 15:16

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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 ☐

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:02
PC Open Date & Time	04 AUG 2020 16:11
PC Close Date & Time	05 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

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)

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US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:09
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

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)

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:30
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

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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US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:34
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:16
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:37
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

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)

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3832074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 08:15
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

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

SUBJECT DECLINED TO RECEIVE INJECTION AT DAY 29 VISIT, BUT WISHES TO CONTINUE STUDY PARTICIPATION AS PER PROTOCOL.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3832074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 SEP 2020

Collection time (00:00-23:59)

08:26 (24 HR)

Collection date and time (derived)

4 SEP 2020 08:26

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:28	4 SEP 2020 08:28
Nasopharyngeal Swab 2	No		

US3832074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:04:26

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:04:26

Generated On: 10 Jun 2021 10:03:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:28 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 09:28
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:04:26

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3832074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	09:44 (24 HR)
Collection date and time (derived)	6 OCT 2020 09:44

US3832074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:04:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 09:52:47

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 05:30:59

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 07:29:26

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 19:35:42

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 11:14:52

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 08:13:03

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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 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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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 <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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

07 DEC 2020 07:43:52

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 13:16:44
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

20 DEC 2020 18:30:16

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 16:23:32

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 10:02:08

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

07 JAN 2021 00:03:03

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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	14 JAN 2021 08:46:25
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

25 JAN 2021 12:50:36

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:03:24

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 16:20:20

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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	11 FEB 2021 16:15:27
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 09:02:13

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 15:27:34

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 11:23:23

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 07:40:33

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 15:13:00

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 17:52:11

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 10:53:44

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 19:01:50

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 12:32:56

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 06:38:45

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:46:17

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

10 MAY 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

17 MAY 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

24 MAY 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

31 MAY 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

07 JUN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

14 JUN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

21 JUN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

28 JUN 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

05 JUL 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

12 JUL 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

19 JUL 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

26 JUL 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

02 AUG 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

09 AUG 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

16 AUG 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

23 AUG 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

30 AUG 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

06 SEP 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

13 SEP 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

20 SEP 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

27 SEP 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

04 OCT 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

11 OCT 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

18 OCT 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

25 OCT 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

01 NOV 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2021 00:01

Patient Cloud Close Date & Time

08 NOV 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

15 NOV 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2021 00:01

Patient Cloud Close Date & Time

22 NOV 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

29 NOV 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

06 DEC 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

13 DEC 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

20 DEC 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

27 DEC 2021 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

03 JAN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

10 JAN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

17 JAN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

24 JAN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

31 JAN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

07 FEB 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

14 FEB 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

21 FEB 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

28 FEB 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

07 MAR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

14 MAR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

21 MAR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

28 MAR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

04 APR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

11 APR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

18 APR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

25 APR 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Patient Cloud Close Date & Time

02 MAY 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 MAY 2022 00:01

Patient Cloud Close Date & Time

09 MAY 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAY 2022 00:01

Patient Cloud Close Date & Time

16 MAY 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 MAY 2022 00:01

Patient Cloud Close Date & Time

23 MAY 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 MAY 2022 00:01

Patient Cloud Close Date & Time

30 MAY 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JUN 2022 00:01

Patient Cloud Close Date & Time

06 JUN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JUN 2022 00:01

Patient Cloud Close Date & Time

13 JUN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JUN 2022 00:01

Patient Cloud Close Date & Time

20 JUN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JUN 2022 00:01

Patient Cloud Close Date & Time

27 JUN 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUN 2022 00:01

Patient Cloud Close Date & Time

04 JUL 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JUL 2022 00:01

Patient Cloud Close Date & Time

11 JUL 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JUL 2022 00:01

Patient Cloud Close Date & Time

18 JUL 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JUL 2022 00:01

Patient Cloud Close Date & Time

25 JUL 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JUL 2022 00:01

Patient Cloud Close Date & Time

01 AUG 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 AUG 2022 00:01

Patient Cloud Close Date & Time

08 AUG 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 AUG 2022 00:01

Patient Cloud Close Date & Time

15 AUG 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 AUG 2022 00:01

Patient Cloud Close Date & Time

22 AUG 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 AUG 2022 00:01

Patient Cloud Close Date & Time

29 AUG 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 SEP 2022 00:01

Patient Cloud Close Date & Time

05 SEP 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 SEP 2022 00:01

Patient Cloud Close Date & Time

12 SEP 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 SEP 2022 00:01

Patient Cloud Close Date & Time

19 SEP 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 SEP 2022 00:01

Patient Cloud Close Date & Time

26 SEP 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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="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"/>

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 SEP 2022 00:01

Patient Cloud Close Date & Time

03 OCT 2022 23:59

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2022 00:01

Patient Cloud Close Date & Time

10 OCT 2022 23:59

US3832074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:03:19

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		04 MAR 2021 11:07:35

US3832074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

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

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 12:07:22

Generated On: 10 Jun 2021 10:03:19

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3832074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

10:13 (24 HR)

Collection date and time (derived)

22 FEB 2021 10:13

US3832074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 18:40:37

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 18:40:37

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832074

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:03:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832074

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

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

Visit date (dd MMM yyyy)	5 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3832074

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 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>)	5 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input 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	1
Continuing with mRNA-1273	1

US3832074

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Height	66.0 in
Weight	181.0 lb
BMI (xxx.x)	29.27525

US3832074

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Height	66.0 in
Weight	181.0 lb
BMI (xxx.x)	29.27525
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)	5 JAN 2021
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 12:04
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3832074

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Height	66.0 in
Weight	181.0 lb
BMI (xxx.x)	29.27525
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)	5 JAN 2021
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 12:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3832074

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3832074

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

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) 5 JAN 2021

What was the treatment time? (00:00-23:59) 12:14 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 12:14

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

US3832074

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 JAN 2021

Collection time (00:00-23:59)

11:57 (24 HR)

Collection date and time (derived)

5 JAN 2021 11:57

US3832074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	11:53
Collection Date and Time (derived)	5 JAN 2021 11:53

US3832074

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:01:25

Generated On: 10 Jun 2021 10:03:19

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

US3832074

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

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)	22 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 10:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:02
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 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

US3832074

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3832074

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

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) 22 FEB 2021

What was the treatment time? (00:00-23:59) 10:31 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 10:31

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

US3832074

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:07:11

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:03:25

Generated On: 10 Jun 2021 10:03:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832074

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 22:12:28

Generated On: 10 Jun 2021 10:03:19

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832074

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

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.

US3832074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	25 MAR 2021 10:15

US3832074

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

AEID	USA-US100-2020-MRNA-1273-P30 1000002
Adverse event	ST ELEVATION MYOCARDIAL INFARCTION (UNSPECIFIED ARTERY)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 SEP 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)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		True
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

AT DAY 43 SAFETY CALL,
SUBJECT REPORTED CURRENT
HOSPITAL ADMISSION DUE TO
MYOCARDIAL INFARCTION.

SUBJECT STATES SHE WAS
ADMITTED ON 16SEP2020 AND
WAS TOLD SHE WOULD LIKELY
BE DISCHARGED ON 19SEP2020.

SUBJECT REPORTS RECEIVING
MEDICATIONS DURING
ADMISSION BUT UNABLE TO
RECALL THE NAMES/DOSES AT
THIS TIME. SUBJECT REPORTS

HAVING PROCEDURE
PERFORMED, BUT CANNOT
RECALL NAME. SUBJECT
INSTRUCTED TO CONTACT
OFFICE FOR MEDICAL RECORD

RELEASE AUTHORIZATION
UPON DISCHARGE. SUBJECT
VERBALIZED

UNDERSTANDING. WILL
UPDATE UPON RECEIPT AND
REVIEW OF MEDICAL

RECORDS. UPDATED 06/10/2020
EVENT TERM UPDATED TO ST
ELEVATION MYOCARDIAL

INFARCTION (UNSPECIFIED
ARTERY) UNCLEAR IF
PRIMARY CARDIAC EVENT V'S

UNCONTROLLED
HYPERTENSION PROCEDURES,
CONCOMITANT MEDICATIONS,

AND LABS OBTAINED
UPDATED AS PER MEDICAL
RECORD REVIEW

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3832074

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

AEID

Adverse event

RIGHT WRIST FRACTURE

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)

15 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

AEID

Adverse event

LUMBAR BACK PAIN

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)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 SEP 2020

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:12:27

Generated On: 10 Jun 2021 10:03:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:01:24

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication SIMVASTATION

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication LUMBAR BACK PAIN

Dose per administration 220

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 08 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication AE - MYOCARDIAL
INFARCTION

Dose per administration 0.4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication ISOSORBIDE MONONITRATE

Prophylaxis Yes ☐
No ☒

Indication AE - MYOCARDIAL
INFARCTION

Dose per administration 30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication AE - MYOCARDIAL
INFARCTION

Dose per administration 75

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication DYSLIPIDEMIA

Dose per administration 20

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication BENADRYL

Prophylaxis Yes ☒
No ☐

Indication SLEEP AID

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication PEPCID (FAMOTIDINE)

Prophylaxis Yes ☒
No ☐

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT -
MYOCARDIAL INFARCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 17:01:23

Generated On: 10 Jun 2021 10:03:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 SEP 2020	CHEST X-RAY	Adverse Event	
16 SEP 2020	LCH- ATTEMPTED PCI TO RCA UNSUCCESSFUL	Adverse Event	
16 SEP 2020	CARDIAC ECHO: NOTED LOW NORMAL LEFT VENTRICLE SYSTOLIC FUNCTION, GRADE 1 LEFT VENTRICULAR DIASTOLIC DYSFUNCTION	Adverse Event	
16 SEP 2020	LABS OBTAINED ALL NOTED WITHIN NORMAL LIMITS WITH THE EXCEPTION OF GLUCOSE NOTED AT 144	Adverse Event	
17 SEP 2020	HEART CATHERIZATION	Adverse Event	

US3832074

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

Date of dosing discontinuation (dd MMM yyyy) 4 SEP 2020

Primary reason for dosing discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT DID NOT WITHDRAW CONSENT FOR THE STUDY, BUT DID NOT WISH TO RECEIVE SECOND IP DOSE. SUBJECT AGREED TO CONTINUE STUDY PARTICIPATION WITH ALL OTHER PROCEDURES/ASSESSMENTS PER PROTOCOL.
---	--

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

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 ☐

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:45
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:32
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/OCT/2020 17:57
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/OCT/2020 15:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/NOV/2020 22:11
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	04/DEC/2020 20:40
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/JAN/2021 08:36
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

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 21 Feb 2021 17:01:24

Generated On: 10 Jun 2021 10:03:19

SAEID	USA-US100-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/FEB/2021 10:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3832074 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832074

Form: Participant Creation

Generated On: 10 Jun 2021 10:03:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'US3832074'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 15:29:27

US3832074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:09:40

US3832074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:04:38
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 15:29:28

US3832074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:38
User entered 'Clinic (Clinic)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:09:40

US3832074

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'SCRN'	System	04 Aug 2020 16:09:40

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:04:56
User entered (b) (6) 1938'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 15:29:29

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '82'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'YEARS'	System	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '82'	System	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered 'Female (F)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered 'l'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:03:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:58
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:08

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Aug 2020'	System	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2020'	System	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered 'Amendment 1 (1)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:26

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:07:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 15:29:28

US3832074

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:03:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'I'	System	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:07:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:03:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:08:39
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:43

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:11:56
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) (b) (4)	04 Aug 2020 16:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:13:00
Data point term sent to Coder	System	04 Aug 2020 16:11:25
User entered 'Hyperlipidemia'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:11:56
User entered 'un UNK 2005'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:11:56
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:11:56
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:11:56
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:11:56
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	04 Aug 2020 16:10:59

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Aug 2020 16:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 16:13:01
Data point term sent to Coder	System	04 Aug 2020 16:11:25
User entered 'Hypertension'	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12
	(b) (4)	

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'un UNK 2005'	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	04 Aug 2020 16:11:12

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:26:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:26:03
Data point term sent to Coder	System	20 Oct 2020 19:24:41
User entered 'Hysterectomy'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'UN UNK 2005'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'UN UNK 2005'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	20 Oct 2020 19:23:51

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:26:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:26:04
Data point term sent to Coder	System	20 Oct 2020 19:24:47
User entered 'Tubal Ligation'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'UN UNK 1970'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'UN UNK 1970'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 1970'	System	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '1970'	System	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 1970'	System	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '1970'	System	20 Oct 2020 19:24:34

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 17:03:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 17:03:34
Data point term sent to Coder	System	11 Nov 2020 17:02:02
User entered 'Menorrhagia'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'un UNK 2005'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'un UNK 2005'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Danyel Johnson (b) (4)	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2005'	System	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2005'	System	11 Nov 2020 17:01:26

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:16:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:16:50
Data point term sent to Coder	System	14 Apr 2021 19:16:09
User entered 'Intermittent Back Pain'	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'un UNK 2000'	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered '0'	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered '0'	Danyel Johnson (b) (4)	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'Jan 2000'	System	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '2000'	System	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered empty.	System	14 Apr 2021 19:15:31

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '11:45'	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered '04 Aug 2020 11:45'	System	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '167.6' cm	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14
DataPoint set to visible.	System	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '82.1' kg	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14
DataPoint set to visible.	(b) (4) System	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
Amendment Manager: User entered '29.22773'	System	16 Sep 2020 23:42:24
User entered '29.2'	System	04 Aug 2020 16:14:14
DataPoint set to visible.	System	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'kg/m2'	System	04 Aug 2020 16:14:14
DataPoint set to visible.	System	04 Aug 2020 16:10:33

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:22
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:24:23
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:42
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '97.3' F	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:24
Query 'please delete' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:18
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:24:59
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:46
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:26
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:25:08
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '75'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'bpm'	System	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:28
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:25:17
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '14'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'breaths/min'	System	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:30
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:25:24
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '147'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'mmHg'	System	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:31
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'UPDATED PER QUERY ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:08:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:07:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:25:31
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:22:15
User entered '78'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User entered 'mmHg'	System	04 Aug 2020 16:14:14

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56

US3832074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56

US3832074

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:14:28

US3832074

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 09:03:54
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 12:14:01
User entered '04 Aug 2020'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:14:28

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:53:22
Query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' answered with 'please see log line 4 medical history ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:33:50
User opened query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:49:46
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:49:21
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	20 Oct 2020 19:24:54
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:52:39
User entered 'Surgically sterile (SURGICALLY STERILE)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'un UNK 1970'	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:03:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:15:08

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:17:51
' (Site from CRA).		
Query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry.	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:40:36
' answered with 'updated ' (Site from CRA).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:40:25
	(b) (4)	
User opened query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry.	(b) (4), (b) (6)	08 Nov 2020 22:17:19
' (Site from CRA).		
User closed query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie unemployed)' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:17:19
Query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie unemployed)' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:09:58
	(b) (4)	
User opened query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie unemployed)' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:09:07
Query 'please comment for working conditions only. please delete as it is captured on demographics	(b) (4), (b) (6)	03 Nov 2020 00:38:33
' canceled (Site from CRA).		
User opened query 'please comment for working conditions only. please delete as it is captured on demographics	(b) (4), (b) (6)	03 Nov 2020 00:20:37
' (Site from CRA).		
Query 'please remove' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:19:59
User opened query 'please remove' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:18:55
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18
	(b) (4)	

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry." (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:17:54
Query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry." answered with 'deleted per query ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:40:47
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:40:25
User opened query "This is for employment that puts subject at risk. "Retired" is not an employment risk - please delete this entry." (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:17:31
User closed query 'per EDC guidelines, this section is for occupation only. please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:17:31
Query 'per EDC guidelines, this section is for occupation only. please review and reconcile.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:10:08
User entered 'Retired' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:06:35
User opened query 'per EDC guidelines, this section is for occupation only. please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:09:35
Query 'please comment for working conditions only. please delete as it is captured on demographics ' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:38:30
User opened query 'please comment for working conditions only. please delete as it is captured on demographics ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:20:46
Query "This section is for living conditions. please delete this ' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:20:01
User opened query "This section is for living conditions. please delete this ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:19:13
User entered 'participant has attended large group events in the past few weeks'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:00
Query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' ' answered with 'updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:40:57
User entered '0' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:40:25
User opened query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:15:42
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 17:04:00
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:04:00
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 17:03:38
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '0'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:40:25
User entered '0'	(b) (4)	
	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18
	(b) (4)	

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:09:40
Query 'Please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:03:55
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 17:03:38
User opened query 'Please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:38:57
User entered '1'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:03:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:15:56
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:09:42
Query 'This section is for living conditions, please verify and reconcile.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 17:03:52
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 17:03:38
User opened query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:39:24
User entered 'participant plan on routinely (e.g., weekly) going to places where people gather'	Ashten Sheriff (b) (4)	04 Aug 2020 16:16:18

US3832074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:30:02

US3832074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:30:02

US3832074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:30:02

US3832074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'VISIT1'	System	04 Aug 2020 16:30:02

US3832074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:56:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:56:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 16:04:38
User entered '184591' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:01:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:01:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:01:54

US3832074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:01:54

US3832074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:03:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:01:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:14
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:31
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:59
User entered '167.6' cm	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:16
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:38
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:03
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:08:04
User entered '82.1' kg	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:14
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:31
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:59
User entered '167.6' cm	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:16
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:38
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:03
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:08:04
User entered '82.1' kg	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Pre-Dose (PREDOSE)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4) Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '11:45'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '04 Aug 2020 11:45'	System	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '97.3' F	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '75'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'bpm'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '14'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'breaths/min'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '147'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'mmHg'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '78'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'mmHg'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:14
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:06
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:31
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:44
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:59
User entered '167.6' cm	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:16
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:15:45
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:16
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:34:38
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:14:54
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:23:03
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:22:56
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:08:04
User entered '82.1' kg	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Post-Dose (POSTDOSE)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 13:06:20
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 22:03:54
User entered '12:56'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '04 Aug 2020 12:56'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '97.9' F	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '72'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'bpm'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '16'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'breaths/min'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '130'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'mmHg'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '79'	Ashten Sheriff (b) (4)	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'mmHg'	System	04 Aug 2020 22:03:54

US3832074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:14:14
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:36:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 18:36:28
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:36:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:36:19
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:36:19
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:33
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:04:06

US3832074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'please remove date' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:14:20
Query 'please remove date' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:36:39
User entered empty; reason for change Data Entry Error	(b) (4) Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:36:19
User opened query 'please remove date' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:41
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:06
	(b) (4)	

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '12:26'	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '04 Aug 2020 12:26'	System	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'ONCE'	System	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 16:34:51

US3832074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:27

US3832074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:27

US3832074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '12:11'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:27

US3832074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '04 Aug 2020 12:11'	System	04 Aug 2020 22:04:27

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '04 Aug 2020'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ashten Sheriff (b) (4) (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '12:10'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '04 Aug 2020 12:10'	System	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 22:02:53
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 22:02:53
User entered '12:10'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	10 Nov 2020 22:02:53
User entered '04 Aug 2020 12:10'	System	04 Aug 2020 22:04:47

US3832074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	04 Aug 2020 22:04:54

US3832074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	04 Aug 2020 22:04:54

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T12:59:35', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '851c07da-4ec4-45e7-8c32-915dcf44b0e1' User entered 'Yes (Y)'	System	04 Aug 2020 17:00:43
	System	04 Aug 2020 17:00:43

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T12:59:55', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '851c07da-4ec4-45e7-8c32-915dcf44b0e1' User entered '97.9'	System	04 Aug 2020 17:00:43
	System	04 Aug 2020 17:00:43

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:00:20', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '851c07da-4ec4-45e7-8c32-915dcf44b0e1' User entered 'No (N)'	System	04 Aug 2020 17:00:43
	System	04 Aug 2020 17:00:43

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:00:41', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '851c07da-4ec4-45e7-8c32-915dcf44b0e1' User entered '04 Aug 2020 13:00'	System	04 Aug 2020 17:00:43
	System	04 Aug 2020 17:00:43

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 12:46'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 15:16'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:00:12', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '3e373fb3-e313-4215-b30b-c2ed09c8903d' User entered 'Yes (Y)'	System	04 Aug 2020 23:00:44
	System	04 Aug 2020 23:00:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T18:59:56', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '3e373fb3-e313-4215-b30b-c2ed09c8903d' User entered '97.2'	System	04 Aug 2020 23:00:44
	System	04 Aug 2020 23:00:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:00:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '3e373fb3-e313-4215-b30b-c2ed09c8903d' User entered 'No (N)'	System	04 Aug 2020 23:00:44
	System	04 Aug 2020 23:00:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:00:40', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '3e373fb3-e313-4215-b30b-c2ed09c8903d' User entered '04 Aug 2020 19:00'	System	04 Aug 2020 23:00:44
	System	04 Aug 2020 23:00:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 2'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:04:55', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '16ec3021-60fe-4fed-a296-334caf1c2882' User entered 'Yes (Y)'	System	05 Aug 2020 23:06:44
	System	05 Aug 2020 23:06:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:06:04', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '16ec3021-60fe-4fed-a296-334caf1c2882'	System	05 Aug 2020 23:06:44
User entered '98.6'	System	05 Aug 2020 23:06:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:05:04', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '16ec3021-60fe-4fed-a296-334caf1c2882'	System	05 Aug 2020 23:06:44
User entered 'No (N)'	System	05 Aug 2020 23:06:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:06:42', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '16ec3021-60fe-4fed-a296-334caf1c2882'	System	05 Aug 2020 23:06:44
User entered '05 Aug 2020 19:06'	System	05 Aug 2020 23:06:44

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 3'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:27:48', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '184123ba-4759-4280-bffb-64a9094013df' User entered 'Yes (Y)'	System	06 Aug 2020 22:28:15
	System	06 Aug 2020 22:28:15

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:27:20', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '184123ba-4759-4280-bffb-64a9094013df' User entered '97.6'	System	06 Aug 2020 22:28:15
	System	06 Aug 2020 22:28:15

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:27:24', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '184123ba-4759-4280-bffb-64a9094013df' User entered 'No (N)'	System	06 Aug 2020 22:28:15
	System	06 Aug 2020 22:28:15

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:28:09', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '184123ba-4759-4280-bffb-64a9094013df' User entered '06 Aug 2020 18:28'	System	06 Aug 2020 22:28:15
	System	06 Aug 2020 22:28:15

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 4'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:31:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5e68e580-79de-4c01-84e4-fd5dcba63118' User entered 'Yes (Y)'	System	07 Aug 2020 23:33:07
	System	07 Aug 2020 23:33:07

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:32:26', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5e68e580-79de-4c01-84e4-fd5dcba63118' User entered '97.0'	System	07 Aug 2020 23:33:07
	System	07 Aug 2020 23:33:07

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:32:31', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5e68e580-79de-4c01-84e4-fd5dcba63118'	System	07 Aug 2020 23:33:07
User entered 'No (N)'	System	07 Aug 2020 23:33:07

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:05', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5e68e580-79de-4c01-84e4-fd5dcba63118' User entered '07 Aug 2020 19:33'	System	07 Aug 2020 23:33:07
	System	07 Aug 2020 23:33:07

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 5'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:06', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c2a6bbb2-7518-4109-906d-57689e92b045'	System	09 Aug 2020 00:15:21
User entered 'Yes (Y)'	System	09 Aug 2020 00:15:21

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:14:51', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c2a6bbb2-7518-4109-906d-57689e92b045'	System	09 Aug 2020 00:15:21
User entered '98.6'	System	09 Aug 2020 00:15:21

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:14:56', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c2a6bbb2-7518-4109-906d-57689e92b045'	System	09 Aug 2020 00:15:21
User entered 'No (N)'	System	09 Aug 2020 00:15:21

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:17', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c2a6bbb2-7518-4109-906d-57689e92b045'	System	09 Aug 2020 00:15:21
User entered '08 Aug 2020 20:15'	System	09 Aug 2020 00:15:21

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 6'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:01', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '8df7f9bd-3b8f-48fa-a339-0f3d125569d7' User entered 'Yes (Y)'	System	09 Aug 2020 22:36:48
	System	09 Aug 2020 22:36:48

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '8df7f9bd-3b8f-48fa-a339-0f3d125569d7' User entered '98.6'	System	09 Aug 2020 22:36:48
	System	09 Aug 2020 22:36:48

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:30', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '8df7f9bd-3b8f-48fa-a339-0f3d125569d7'	System	09 Aug 2020 22:36:48
User entered 'No (N)'	System	09 Aug 2020 22:36:48

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:43', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '8df7f9bd-3b8f-48fa-a339-0f3d125569d7'	System	09 Aug 2020 22:36:48
User entered '09 Aug 2020 18:36'	System	09 Aug 2020 22:36:48

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 7'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:47:01', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f79a4791-7aa2-45fa-8144-1b51f263ad8a' User entered 'Yes (Y)'	System	10 Aug 2020 22:47:30
	System	10 Aug 2020 22:47:30

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:47:12', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f79a4791-7aa2-45fa-8144-1b51f263ad8a' User entered '98.6'	System	10 Aug 2020 22:47:30
	System	10 Aug 2020 22:47:30

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:47:17', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f79a4791-7aa2-45fa-8144-1b51f263ad8a'	System	10 Aug 2020 22:47:30
User entered 'No (N)'	System	10 Aug 2020 22:47:30

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:47:25', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f79a4791-7aa2-45fa-8144-1b51f263ad8a' User entered '10 Aug 2020 18:47'	System	10 Aug 2020 22:47:30
	System	10 Aug 2020 22:47:30

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:01:07', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'bef62592-bbf3-4255-be30-d52c73dd7f17'	System	04 Aug 2020 17:01:45
User entered 'None (1)'	System	04 Aug 2020 17:01:45

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:01:19', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'bef62592-bbf3-4255-be30-d52c73dd7f17'	System	04 Aug 2020 17:01:45
User entered 'No (N)'	System	04 Aug 2020 17:01:45

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:01:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'bef62592-bbf3-4255-be30-d52c73dd7f17'	System	04 Aug 2020 17:01:45
User entered 'No (N)'	System	04 Aug 2020 17:01:45

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:01:30', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'bef62592-bbf3-4255-be30-d52c73dd7f17'	System	04 Aug 2020 17:01:45
User entered 'None (1)'	System	04 Aug 2020 17:01:45

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:01:43', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'bef62592-bbf3-4255-be30-d52c73dd7f17' User entered '04 Aug 2020 13:01'	System	04 Aug 2020 17:01:45
	System	04 Aug 2020 17:01:45

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 12:46'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 15:16'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f96294a4-7657-4ca1-bf97-7376b2de928a' User entered 'None (1)'	System	04 Aug 2020 23:01:44
	System	04 Aug 2020 23:01:44

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:07', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f96294a4-7657-4ca1-bf97-7376b2de928a' User entered 'No (N)'	System	04 Aug 2020 23:01:44
	System	04 Aug 2020 23:01:44

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:12', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f96294a4-7657-4ca1-bf97-7376b2de928a' User entered 'No (N)'	System	04 Aug 2020 23:01:44
	System	04 Aug 2020 23:01:44

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:21', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f96294a4-7657-4ca1-bf97-7376b2de928a' User entered 'None (1)'	System	04 Aug 2020 23:01:44
	System	04 Aug 2020 23:01:44

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:41', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f96294a4-7657-4ca1-bf97-7376b2de928a' User entered '04 Aug 2020 19:01'	System	04 Aug 2020 23:01:44
	System	04 Aug 2020 23:01:44

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 2'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:07:19', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '567c17c0-6f1e-4558-b879-6ad1be894eb9' User entered 'None (1)'	System	05 Aug 2020 23:08:14
	System	05 Aug 2020 23:08:14

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:07:27', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '567c17c0-6f1e-4558-b879-6ad1be894eb9' User entered 'No (N)'	System	05 Aug 2020 23:08:14
	System	05 Aug 2020 23:08:14

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:07:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '567c17c0-6f1e-4558-b879-6ad1be894eb9' User entered 'No (N)'	System	05 Aug 2020 23:08:14
	System	05 Aug 2020 23:08:14

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:07:51', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '567c17c0-6f1e-4558-b879-6ad1be894eb9' User entered 'None (1)'	System	05 Aug 2020 23:08:14
	System	05 Aug 2020 23:08:14

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '567c17c0-6f1e-4558-b879-6ad1be894eb9' User entered '05 Aug 2020 19:08'	System	05 Aug 2020 23:08:14
	System	05 Aug 2020 23:08:14

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 3'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:28:49', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f838ea01-faf8-43c9-8cab-80ca88089f83'	System	06 Aug 2020 22:29:12
User entered 'None (1)'	System	06 Aug 2020 22:29:12

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:28:28', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f838ea01-faf8-43c9-8cab-80ca88089f83'	System	06 Aug 2020 22:29:12
User entered 'No (N)'	System	06 Aug 2020 22:29:12

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:28:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f838ea01-faf8-43c9-8cab-80ca88089f83'	System	06 Aug 2020 22:29:12
User entered 'No (N)'	System	06 Aug 2020 22:29:12

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:28:37', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f838ea01-faf8-43c9-8cab-80ca88089f83'	System	06 Aug 2020 22:29:12
User entered 'None (1)'	System	06 Aug 2020 22:29:12

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:10', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f838ea01-faf8-43c9-8cab-80ca88089f83'	System	06 Aug 2020 22:29:12
User entered '06 Aug 2020 18:29'	System	06 Aug 2020 22:29:12

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 4'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:18', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e882b838-91f9-48ac-93be-cbe0f06cfa55'	System	07 Aug 2020 23:33:41
User entered 'None (1)'	System	07 Aug 2020 23:33:41

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:22', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e882b838-91f9-48ac-93be-cbe0f06cfa55'	System	07 Aug 2020 23:33:41
User entered 'No (N)'	System	07 Aug 2020 23:33:41

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:27', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e882b838-91f9-48ac-93be-cbe0f06cfa55'	System	07 Aug 2020 23:33:41
User entered 'No (N)'	System	07 Aug 2020 23:33:41

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e882b838-91f9-48ac-93be-cbe0f06cfa55'	System	07 Aug 2020 23:33:41
User entered 'None (1)'	System	07 Aug 2020 23:33:41

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:39', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e882b838-91f9-48ac-93be-cbe0f06cfa55'	System	07 Aug 2020 23:33:41
User entered '07 Aug 2020 19:33'	System	07 Aug 2020 23:33:41

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 5'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:10', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd9990d92-3ebd-40bd-955e-4c557ea0e463'	System	09 Aug 2020 00:16:43
User entered 'None (1)'	System	09 Aug 2020 00:16:43

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:16', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd9990d92-3ebd-40bd-955e-4c557ea0e463' User entered 'No (N)'	System	09 Aug 2020 00:16:43
	System	09 Aug 2020 00:16:43

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:20', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd9990d92-3ebd-40bd-955e-4c557ea0e463' User entered 'No (N)'	System	09 Aug 2020 00:16:43
	System	09 Aug 2020 00:16:43

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:24', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd9990d92-3ebd-40bd-955e-4c557ea0e463'	System	09 Aug 2020 00:16:43
User entered 'None (1)'	System	09 Aug 2020 00:16:43

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:39', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd9990d92-3ebd-40bd-955e-4c557ea0e463'	System	09 Aug 2020 00:16:43
User entered '08 Aug 2020 20:16'	System	09 Aug 2020 00:16:43

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 6'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:50', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '86f76b6e-0902-493a-8573-f75844a463e4' User entered 'None (1)'	System	09 Aug 2020 22:37:18
	System	09 Aug 2020 22:37:18

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:54', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '86f76b6e-0902-493a-8573-f75844a463e4' User entered 'No (N)'	System	09 Aug 2020 22:37:18
	System	09 Aug 2020 22:37:18

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:36:58', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '86f76b6e-0902-493a-8573-f75844a463e4' User entered 'No (N)'	System	09 Aug 2020 22:37:18
	System	09 Aug 2020 22:37:18

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:02', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '86f76b6e-0902-493a-8573-f75844a463e4' User entered 'None (1)'	System	09 Aug 2020 22:37:18
	System	09 Aug 2020 22:37:18

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:14', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '86f76b6e-0902-493a-8573-f75844a463e4' User entered '09 Aug 2020 18:37'	System	09 Aug 2020 22:37:18
	System	09 Aug 2020 22:37:18

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 7'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:47:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5eafb9e2-696d-4458-8b3e-43f6d14b962a' User entered 'None (1)'	System	10 Aug 2020 22:48:56
	System	10 Aug 2020 22:48:56

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:48:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5eafb9e2-696d-4458-8b3e-43f6d14b962a' User entered 'No (N)'	System	10 Aug 2020 22:48:56
	System	10 Aug 2020 22:48:56

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:48:28', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5eafb9e2-696d-4458-8b3e-43f6d14b962a' User entered 'No (N)'	System	10 Aug 2020 22:48:56
	System	10 Aug 2020 22:48:56

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:48:42', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5eafb9e2-696d-4458-8b3e-43f6d14b962a' User entered 'None (1)'	System	10 Aug 2020 22:48:56
	System	10 Aug 2020 22:48:56

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-10T18:48:55', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '5eafb9e2-696d-4458-8b3e-43f6d14b962a' User entered '10 Aug 2020 18:48'	System	10 Aug 2020 22:48:56
	System	10 Aug 2020 22:48:56

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:26', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:35', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:38', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:41', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'None (0)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:02:46', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered 'No (N)'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T13:03:02', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'f99405a3-29ba-4d60-b89d-4378b6478b64' User entered '04 Aug 2020 13:03'	System	04 Aug 2020 17:03:05
	System	04 Aug 2020 17:03:05

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 12:46'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 15:16'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:01:59', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:04', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:08', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:17', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:21', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:24', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'None (0)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:29', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered 'No (N)'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-04T19:02:51', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c6a471f4-efc8-4c34-88d4-138d2a3610ba' User entered '04 Aug 2020 19:02'	System	04 Aug 2020 23:02:55
	System	04 Aug 2020 23:02:55

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 2'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:24', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered 'None (0)'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:28', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb'	System	05 Aug 2020 23:09:24
User entered 'None (0)'	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:33', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered 'None (0)'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered 'None (0)'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:40', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered 'None (0)'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:52', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered 'None (0)'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:08:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb'	System	05 Aug 2020 23:09:24
User entered 'No (N)'	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-05T19:09:20', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ab4044c4-019f-4efe-957d-6be37e9895bb' User entered '05 Aug 2020 19:09'	System	05 Aug 2020 23:09:24
	System	05 Aug 2020 23:09:24

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 3'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:29', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:40', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:43', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:46', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'None (0)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:29:50', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered 'No (N)'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-06T18:30:04', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '1f4e8c3c-ee0b-4a67-9114-926766f5f731' User entered '06 Aug 2020 18:30'	System	06 Aug 2020 22:30:06
	System	06 Aug 2020 22:30:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 4'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:47', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered 'None (0)'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:51', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54'	System	07 Aug 2020 23:34:44
User entered 'None (0)'	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:54', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered 'None (0)'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:33:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered 'None (0)'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:34:01', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered 'None (0)'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:34:03', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered 'None (0)'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:34:10', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54'	System	07 Aug 2020 23:34:44
User entered 'No (N)'	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-07T19:34:41', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd1ed5f5a-704a-43c3-8942-5f8a5fc2fd54' User entered '07 Aug 2020 19:34'	System	07 Aug 2020 23:34:44
	System	07 Aug 2020 23:34:44

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 5'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:39', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:43', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:46', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:50', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'None (0)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:15:55', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered 'No (N)'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-08T20:16:03', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '37d12284-9de1-4009-9aad-85dd820775bd' User entered '08 Aug 2020 20:16'	System	09 Aug 2020 00:16:06
	System	09 Aug 2020 00:16:06

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 6'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:26', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:30', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:34', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:37', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:40', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered 'None (0)'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:46', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6' User entered 'No (N)'	System	09 Aug 2020 22:38:02
	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-08-09T18:37:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '2207eb74-4f0d-4130-8e5d-3c1cd2d6d4f6'	System	09 Aug 2020 22:38:02
User entered '09 Aug 2020 18:37'	System	09 Aug 2020 22:38:02

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 7'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

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 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:34:51

US3832074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:03:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	11 Aug 2020 18:33:08

US3832074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '11 Aug 2020'	Alyssa-Kay Peay (b) (4)	11 Aug 2020 18:33:08

US3832074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	11 Aug 2020 18:33:08

US3832074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Alyssa-Kay Peay (b) (4)	11 Aug 2020 18:33:08

US3832074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	11 Aug 2020 18:33:14

US3832074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	11 Aug 2020 18:33:14

US3832074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 13:37:16

US3832074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 13:37:16

US3832074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 13:37:16

US3832074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 13:37:16

US3832074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 13:37:26

US3832074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	18 Aug 2020 13:37:26

US3832074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	25 Aug 2020 13:36:25

US3832074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '25 Aug 2020'	Emma Partin (b) (4)	25 Aug 2020 13:36:25

US3832074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	25 Aug 2020 13:36:25

US3832074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	25 Aug 2020 13:36:25

US3832074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	25 Aug 2020 13:36:29

US3832074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	25 Aug 2020 13:36:29

US3832074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:14:01

US3832074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '4 Sep 2020'	(b) (4)	04 Sep 2020 12:14:01
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:14:01

US3832074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'VISIT2'	System	04 Sep 2020 12:14:01

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '4 Sep 2020'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '08:15'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered '4 Sep 2020 08:15'	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '98.0' F	(b) (4), (b) (6)	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Oral (Oral)'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '71'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'bpm'	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '14'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'breaths/min'	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 19:20:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 15:53:22
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Sep 2020 15:52:58
User entered '157'	(b) (4), (b) (6)	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'mmHg'	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '79'	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'mmHg'	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:22:09
Query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' answered with 'IP was not administer at this visit ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	21 Oct 2020 18:48:13
User opened query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:23:54
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered empty.	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered empty.	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered empty.	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered empty.	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 15:52:58
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered empty.	System	04 Sep 2020 15:52:58

US3832074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:28:53

US3832074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '4 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:28:53

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)'	(b) (4)	04 Sep 2020 12:13:22
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Subject declined to receive injection at Day 29 visit, but wishes to continue study participation as per protocol.'	(b) (4), (b) (6)	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 12:13:22
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 12:13:22
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	04 Sep 2020 12:13:22
	(b) (4), (b) (6)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	04 Sep 2020 12:13:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:05

US3832074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:05

US3832074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '08:26'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:05

US3832074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '4 Sep 2020 08:26'	System	04 Sep 2020 12:29:05

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '4 Sep 2020'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '08:28'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered '4 Sep 2020 08:28'	System	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 22:03:07
User entered 'Yes (Y)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:20
	(b) (4)	

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 22:03:07
User entered '08:28'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered empty.	System	10 Nov 2020 22:03:07
User entered '4 Sep 2020 08:28'	System	04 Sep 2020 12:29:20

US3832074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Sep 2020 12:29:22

US3832074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	04 Sep 2020 12:29:22

US3832074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:31:50

US3832074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '11 Sep 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:31:50
	(b) (4)	

US3832074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:31:50

US3832074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:31:50

US3832074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:31:43

US3832074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	16 Sep 2020 17:31:43

US3832074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4)	18 Sep 2020 18:36:35
	(b) (4), (b) (6)	

US3832074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 18:36:35

US3832074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:36:35

US3832074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	(b) (4)	18 Sep 2020 18:36:35
	(b) (4), (b) (6)	

US3832074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:36:39

US3832074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	18 Sep 2020 18:36:39

US3832074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:13:25

US3832074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '29 Sep 2020'	Emma Partin (b) (4)	06 Oct 2020 14:13:25
	(b) (4)	

US3832074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	06 Oct 2020 14:13:25

US3832074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:13:25

US3832074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:13:30

US3832074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	06 Oct 2020 14:13:30

US3832074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:13:44

US3832074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	10 Dec 2020 23:54:50
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '6 Oct 2020'	Emma Partin (b) (4)	06 Oct 2020 14:13:44
	(b) (4)	

US3832074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	06 Oct 2020 14:13:44

US3832074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'VISIT3'	System	06 Oct 2020 14:13:44

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '6 Oct 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '09:28'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered '6 Oct 2020 09:28'	System	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '98.0' F	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Oral (Oral)'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '60'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'bpm'	System	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '14'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'breaths/min'	System	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '151'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'mmHg'	System	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '87'	Emma Partin (b) (4)	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'mmHg'	System	06 Oct 2020 14:14:28

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31

US3832074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31

US3832074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:15:18

US3832074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		10 Dec 2020 19:56:01
User entered '6 Oct 2020'	Emma Partin (b) (4)	06 Oct 2020 14:15:18
	(b) (4)	

US3832074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:16:58

US3832074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	10 Dec 2020 23:54:50
User entered '6 Oct 2020'	System	10 Dec 2020 19:56:01
	Emma Partin (b) (4)	06 Oct 2020 14:16:58
	(b) (4)	

US3832074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered '09:44'	Emma Partin (b) (4)	06 Oct 2020 14:16:58

US3832074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered '6 Oct 2020 09:44'	System	06 Oct 2020 14:16:58

US3832074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:04:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Oct 2020 14:17:03

US3832074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:50:31
User entered 'I'	System	06 Oct 2020 14:17:03

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 64'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-06T09:52:34', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac3730cc-6932-48c5-8701-1b4d17373235'	System	06 Oct 2020 13:52:50
User entered 'No (N)'	System	06 Oct 2020 13:52:50

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-06T09:52:41', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac3730cc-6932-48c5-8701-1b4d17373235'	System	06 Oct 2020 13:52:50
User entered 'No (N)'	System	06 Oct 2020 13:52:50

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-06T09:52:47', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac3730cc-6932-48c5-8701-1b4d17373235' User entered '06 Oct 2020 09:52:47'	System	06 Oct 2020 13:52:50
	System	06 Oct 2020 13:52:50

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 71'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-13T05:29:58', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a7fd1c39-19a9-44d5-bcce-a205af5de6f9'	System	13 Oct 2020 09:31:06
User entered 'No (N)'	System	13 Oct 2020 09:31:06

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-13T05:30:12', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a7fd1c39-19a9-44d5-bcce-a205af5de6f9'	System	13 Oct 2020 09:31:06
User entered 'No (N)'	System	13 Oct 2020 09:31:06

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-13T05:30:59', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a7fd1c39-19a9-44d5-bcce-a205af5de6f9' User entered '13 Oct 2020 05:30:59'	System	13 Oct 2020 09:31:06
	System	13 Oct 2020 09:31:06

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 78'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-19T07:28:54', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ee37790b-44cd-4f59-9ceb-4d575df1a56e'	System	19 Oct 2020 11:29:29
User entered 'No (N)'	System	19 Oct 2020 11:29:29

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-19T07:28:59', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ee37790b-44cd-4f59-9ceb-4d575df1a56e'	System	19 Oct 2020 11:29:29
User entered 'No (N)'	System	19 Oct 2020 11:29:29

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-10-19T07:29:26', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ee37790b-44cd-4f59-9ceb-4d575df1a56e' User entered '19 Oct 2020 07:29:26'	System	19 Oct 2020 11:29:29
	System	19 Oct 2020 11:29:29

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 92'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-01T19:35:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c3aecb53-a7c6-4444-93d1-e575349e9a26'	System	02 Nov 2020 00:35:45
User entered 'No (N)'	System	02 Nov 2020 00:35:45

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-01T19:35:21', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c3aecb53-a7c6-4444-93d1-e575349e9a26'	System	02 Nov 2020 00:35:45
User entered 'No (N)'	System	02 Nov 2020 00:35:45

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-01T19:35:42', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c3aecb53-a7c6-4444-93d1-e575349e9a26' User entered '01 Nov 2020 19:35:42'	System	02 Nov 2020 00:35:45
	System	02 Nov 2020 00:35:45

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 99'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-12T11:14:11', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c5fd79c-19f1-48d8-a857-71a4a7cf1604'	System	12 Nov 2020 16:14:55
User entered 'No (N)'	System	12 Nov 2020 16:14:55

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-12T11:14:25', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c5fd79c-19f1-48d8-a857-71a4a7cf1604'	System	12 Nov 2020 16:14:55
User entered 'No (N)'	System	12 Nov 2020 16:14:55

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-12T11:14:52', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c5fd79c-19f1-48d8-a857-71a4a7cf1604' User entered '12 Nov 2020 11:14:52'	System	12 Nov 2020 16:14:55
	System	12 Nov 2020 16:14:55

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered 'Day 106'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-16T08:12:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '71393a00-5134-4dcd-a53c-01b0f8e304b1' User entered 'No (N)'	System	16 Nov 2020 13:13:08
	System	16 Nov 2020 13:13:08

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-16T08:12:44', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '71393a00-5134-4dcd-a53c-01b0f8e304b1' User entered 'No (N)'	System	16 Nov 2020 13:13:08
	System	16 Nov 2020 13:13:08

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-11-16T08:13:03', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '71393a00-5134-4dcd-a53c-01b0f8e304b1' User entered '16 Nov 2020 08:13:03'	System	16 Nov 2020 13:13:08
	System	16 Nov 2020 13:13:08

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 16:34:51

US3832074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:27:29
Data entry locked.	System	04 Aug 2020 16:34:51
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 16:34:51

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-07T07:43:29', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'b0780bf5-b26b-459a-b5ff-da40d3b75827'	System	07 Dec 2020 12:43:56
User entered 'No (N)'	System	07 Dec 2020 12:43:56

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-07T07:43:35', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'b0780bf5-b26b-459a-b5ff-da40d3b75827'	System	07 Dec 2020 12:43:56
User entered 'No (N)'	System	07 Dec 2020 12:43:56

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-07T07:43:52', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'b0780bf5-b26b-459a-b5ff-da40d3b75827' User entered '07 Dec 2020 07:43:52'	System	07 Dec 2020 12:43:56
	System	07 Dec 2020 12:43:56

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-10T13:16:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '405a63a0-c872-40bb-8f93-aa78b619d3f1'	System	10 Dec 2020 18:16:47
User entered 'No (N)'	System	10 Dec 2020 18:16:47

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-10T13:16:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '405a63a0-c872-40bb-8f93-aa78b619d3f1'	System	10 Dec 2020 18:16:47
User entered 'No (N)'	System	10 Dec 2020 18:16:47

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-10T13:16:44', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '405a63a0-c872-40bb-8f93-aa78b619d3f1' User entered '10 Dec 2020 13:16:44'	System	10 Dec 2020 18:16:47
	System	10 Dec 2020 18:16:47

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-20T18:30:01', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0f308ee9-1a91-450c-b553-de39c2756d1d'	System	20 Dec 2020 23:30:19
User entered 'No (N)'	System	20 Dec 2020 23:30:19
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-20T18:30:05', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0f308ee9-1a91-450c-b553-de39c2756d1d'	System	20 Dec 2020 23:30:19
User entered 'No (N)'	System	20 Dec 2020 23:30:19
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-20T18:30:16', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0f308ee9-1a91-450c-b553-de39c2756d1d'	System	20 Dec 2020 23:30:19
User entered '20 Dec 2020 18:30:16'	System	20 Dec 2020 23:30:19
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-24T16:22:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '26a9c0e5-bb4f-4a69-ba93-ba11f3a0e64d'	System	24 Dec 2020 21:23:37
User entered 'No (N)'	System	24 Dec 2020 21:23:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-24T16:23:21', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '26a9c0e5-bb4f-4a69-ba93-ba11f3a0e64d'	System	24 Dec 2020 21:23:37
User entered 'No (N)'	System	24 Dec 2020 21:23:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2020-12-24T16:23:32', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '26a9c0e5-bb4f-4a69-ba93-ba11f3a0e64d'	System	24 Dec 2020 21:23:37
User entered '24 Dec 2020 16:23:32'	System	24 Dec 2020 21:23:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-02T10:01:49', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '963c96fd-aa28-4634-9172-c3d5ebcb557f'	System	02 Jan 2021 15:02:10
User entered 'No (N)'	System	02 Jan 2021 15:02:10
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-02T10:01:53', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '963c96fd-aa28-4634-9172-c3d5ebcb557f'	System	02 Jan 2021 15:02:10
User entered 'No (N)'	System	02 Jan 2021 15:02:10
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-02T10:02:08', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '963c96fd-aa28-4634-9172-c3d5ebcb557f'	System	02 Jan 2021 15:02:10
User entered '02 Jan 2021 10:02:08'	System	02 Jan 2021 15:02:10
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-07T00:02:42', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '6c30180d-7b1c-4e55-b2e4-3196738229c8'	System	07 Jan 2021 05:03:11
User entered 'No (N)'	System	07 Jan 2021 05:03:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-07T00:02:49', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '6c30180d-7b1c-4e55-b2e4-3196738229c8'	System	07 Jan 2021 05:03:11
User entered 'No (N)'	System	07 Jan 2021 05:03:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-07T00:03:03', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '6c30180d-7b1c-4e55-b2e4-3196738229c8'	System	07 Jan 2021 05:03:11
User entered '07 Jan 2021 00:03:03'	System	07 Jan 2021 05:03:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-14T08:34:54', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '12e39a37-af10-4a64-8b95-499238d2f3bb'	System	14 Jan 2021 13:46:27
User entered 'No (N)'	System	14 Jan 2021 13:46:27
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-14T08:46:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '12e39a37-af10-4a64-8b95-499238d2f3bb'	System	14 Jan 2021 13:46:27
User entered 'No (N)'	System	14 Jan 2021 13:46:27
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-14T08:46:25', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '12e39a37-af10-4a64-8b95-499238d2f3bb'	System	14 Jan 2021 13:46:27
User entered '14 Jan 2021 08:46:25'	System	14 Jan 2021 13:46:27
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-25T12:50:23', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'fe210b2c-9510-41d8-b218-93c2f65b0e8d'	System	25 Jan 2021 17:50:38
User entered 'No (N)'	System	25 Jan 2021 17:50:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-25T12:50:27', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'fe210b2c-9510-41d8-b218-93c2f65b0e8d'	System	25 Jan 2021 17:50:38
User entered 'No (N)'	System	25 Jan 2021 17:50:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-01-25T12:50:36', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'fe210b2c-9510-41d8-b218-93c2f65b0e8d'	System	25 Jan 2021 17:50:38
User entered '25 Jan 2021 12:50:36'	System	25 Jan 2021 17:50:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-01T12:03:10', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '7e3d0b5f-ceee-4e57-b14c-6509b719eec8'	System	01 Feb 2021 17:08:11
User entered 'No (N)'	System	01 Feb 2021 17:08:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-01T12:03:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '7e3d0b5f-ceee-4e57-b14c-6509b719eec8'	System	01 Feb 2021 17:08:11
User entered 'No (N)'	System	01 Feb 2021 17:08:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-01T12:03:24', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '7e3d0b5f-ceee-4e57-b14c-6509b719eec8'	System	01 Feb 2021 17:08:11
User entered '01 Feb 2021 12:03:24'	System	01 Feb 2021 17:08:11
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-04T16:19:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '96598591-7ada-470f-9a9a-b7815b53fdef'	System	04 Feb 2021 21:20:23
User entered 'No (N)'	System	04 Feb 2021 21:20:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-04T16:20:04', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '96598591-7ada-470f-9a9a-b7815b53fdef'	System	04 Feb 2021 21:20:23
User entered 'No (N)'	System	04 Feb 2021 21:20:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-04T16:20:20', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '96598591-7ada-470f-9a9a-b7815b53fdef'	System	04 Feb 2021 21:20:23
User entered '04 Feb 2021 16:20:20'	System	04 Feb 2021 21:20:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-11T16:15:14', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c2bd224-3216-459a-9eef-e580c6782764'	System	11 Feb 2021 21:15:32
User entered 'No (N)'	System	11 Feb 2021 21:15:32
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-11T16:15:19', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c2bd224-3216-459a-9eef-e580c6782764'	System	11 Feb 2021 21:15:32
User entered 'No (N)'	System	11 Feb 2021 21:15:32
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-11T16:15:27', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '9c2bd224-3216-459a-9eef-e580c6782764'	System	11 Feb 2021 21:15:32
User entered '11 Feb 2021 16:15:27'	System	11 Feb 2021 21:15:32
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-18T09:01:57', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac6bac52-7085-4063-968f-ed7b4238be4b'	System	18 Feb 2021 14:02:18
User entered 'No (N)'	System	18 Feb 2021 14:02:18
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-18T09:02:02', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac6bac52-7085-4063-968f-ed7b4238be4b'	System	18 Feb 2021 14:02:18
User entered 'No (N)'	System	18 Feb 2021 14:02:18
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-18T09:02:13', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'ac6bac52-7085-4063-968f-ed7b4238be4b'	System	18 Feb 2021 14:02:18
User entered '18 Feb 2021 09:02:13'	System	18 Feb 2021 14:02:18
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-26T10:27:06-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '05a5f2f3-8b20-4c0c-9a9b-278574bc1540'	System	26 Feb 2021 15:27:38
User entered 'No (N)'	System	26 Feb 2021 15:27:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-26T10:27:14-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '05a5f2f3-8b20-4c0c-9a9b-278574bc1540'	System	26 Feb 2021 15:27:38
User entered 'No (N)'	System	26 Feb 2021 15:27:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-02-26T10:27:34-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '05a5f2f3-8b20-4c0c-9a9b-278574bc1540'	System	26 Feb 2021 15:27:38
User entered '26 Feb 2021 15:27:34'	System	26 Feb 2021 15:27:38
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-04T11:22:49-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '649dfa4f-d996-4307-99d3-f8b78c5e609d'	System	04 Mar 2021 16:23:42
User entered 'No (N)'	System	04 Mar 2021 16:23:42
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-04T11:22:58-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '649dfa4f-d996-4307-99d3-f8b78c5e609d'	System	04 Mar 2021 16:23:42
User entered 'No (N)'	System	04 Mar 2021 16:23:42
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-04T11:23:23-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '649dfa4f-d996-4307-99d3-f8b78c5e609d'	System	04 Mar 2021 16:23:42
User entered '04 Mar 2021 11:23:23'	System	04 Mar 2021 16:23:42
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-11T07:40:15-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a00e1a4b-a73d-4980-a7e5-5d079c2a02c4'	System	11 Mar 2021 12:40:37
User entered 'No (N)'	System	11 Mar 2021 12:40:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-11T07:40:20-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a00e1a4b-a73d-4980-a7e5-5d079c2a02c4'	System	11 Mar 2021 12:40:37
User entered 'No (N)'	System	11 Mar 2021 12:40:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-11T07:40:33-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'a00e1a4b-a73d-4980-a7e5-5d079c2a02c4'	System	11 Mar 2021 12:40:37
User entered '11 Mar 2021 07:40:33'	System	11 Mar 2021 12:40:37
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-18T15:12:47-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e0d279f3-2a6b-4ee9-8edd-c42f071882b3'	System	18 Mar 2021 19:13:06
User entered 'No (N)'	System	18 Mar 2021 19:13:06
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-18T15:12:53-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e0d279f3-2a6b-4ee9-8edd-c42f071882b3'	System	18 Mar 2021 19:13:06
User entered 'No (N)'	System	18 Mar 2021 19:13:06
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-18T15:13:00-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e0d279f3-2a6b-4ee9-8edd-c42f071882b3'	System	18 Mar 2021 19:13:06
User entered '18 Mar 2021 15:13:00'	System	18 Mar 2021 19:13:06
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-25T17:51:52-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c94fffd-fc1a5-4474-b8f4-9cbf66475ceb'	System	25 Mar 2021 21:52:21
User entered 'No (N)'	System	25 Mar 2021 21:52:21
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-25T17:51:59-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c94fffd-fc1a5-4474-b8f4-9cbf66475ceb'	System	25 Mar 2021 21:52:21
User entered 'No (N)'	System	25 Mar 2021 21:52:21
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-25T17:52:11-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c94fffd-fc1a5-4474-b8f4-9cbf66475ceb'	System	25 Mar 2021 21:52:21
User entered '25 Mar 2021 17:52:11'	System	25 Mar 2021 21:52:21
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-01T10:53:30-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0a92a39f-55e2-4b1d-80ea-86b7772add44'	System	01 Apr 2021 14:53:49
User entered 'No (N)'	System	01 Apr 2021 14:53:49
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-01T10:53:37-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0a92a39f-55e2-4b1d-80ea-86b7772add44'	System	01 Apr 2021 14:53:49
User entered 'No (N)'	System	01 Apr 2021 14:53:49
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-01T10:53:44-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '0a92a39f-55e2-4b1d-80ea-86b7772add44'	System	01 Apr 2021 14:53:49
User entered '01 Apr 2021 10:53:44'	System	01 Apr 2021 14:53:49
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-11T19:01:06-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '31726bd3-2955-46ed-b25f-72ce96c9c399'	System	11 Apr 2021 23:04:23
User entered 'No (N)'	System	11 Apr 2021 23:04:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-11T19:01:41-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '31726bd3-2955-46ed-b25f-72ce96c9c399'	System	11 Apr 2021 23:04:23
User entered 'No (N)'	System	11 Apr 2021 23:04:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-11T19:01:50-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: '31726bd3-2955-46ed-b25f-72ce96c9c399'	System	11 Apr 2021 23:04:23
User entered '11 Apr 2021 19:01:50'	System	11 Apr 2021 23:04:23
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-15T12:32:40-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e104a7b3-e968-4539-8049-58e61c38da95'	System	15 Apr 2021 16:33:00
User entered 'No (N)'	System	15 Apr 2021 16:33:00
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-15T12:32:47-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e104a7b3-e968-4539-8049-58e61c38da95'	System	15 Apr 2021 16:33:00
User entered 'No (N)'	System	15 Apr 2021 16:33:00
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-15T12:32:56-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e104a7b3-e968-4539-8049-58e61c38da95'	System	15 Apr 2021 16:33:00
User entered '15 Apr 2021 12:32:56'	System	15 Apr 2021 16:33:00
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-22T06:38:32-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e58f7594-6ca2-4352-bba7-22e64f9f897d'	System	22 Apr 2021 10:38:47
User entered 'No (N)'	System	22 Apr 2021 10:38:47
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-22T06:38:38-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e58f7594-6ca2-4352-bba7-22e64f9f897d'	System	22 Apr 2021 10:38:47
User entered 'No (N)'	System	22 Apr 2021 10:38:47
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-22T06:38:45-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'e58f7594-6ca2-4352-bba7-22e64f9f897d'	System	22 Apr 2021 10:38:47
User entered '22 Apr 2021 06:38:45'	System	22 Apr 2021 10:38:47
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-29T12:45:53-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c9fb047e-80bf-42e1-aa60-7c7ebaab9ba9'	System	29 Apr 2021 16:46:20
User entered 'No (N)'	System	29 Apr 2021 16:46:20
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you been exposed to someone with known SARS-CoV-2 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 (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-29T12:45:58-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c9fb047e-80bf-42e1-aa60-7c7ebaab9ba9'	System	29 Apr 2021 16:46:20
User entered 'No (N)'	System	29 Apr 2021 16:46:20
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-04-29T12:46:17-04:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'c9fb047e-80bf-42e1-aa60-7c7ebaab9ba9'	System	29 Apr 2021 16:46:20
User entered '29 Apr 2021 12:46:17'	System	29 Apr 2021 16:46:20
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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Folder: New Safety Follow Up Diary (1)

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

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

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[Date and time of submission](#)

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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?

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

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)
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

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Form: Safety Follow Up Diary

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[New loss of smell](#)

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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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DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:29:15

US3832074

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)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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?](#)

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DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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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DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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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)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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DataPoint Inactivated.	System	10 Dec 2020 19:56:01

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

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

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

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US3832074

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:29:15

US3832074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:03:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	10 Dec 2020 23:54:50
DataPoint Inactivated.	System	10 Dec 2020 19:56:01
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:29:15
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:29:15

US3832074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:03:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-04T11:07:20-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd3ba7bbf-2f8e-4da9-ab0c-50d813ee4244'	System	04 Mar 2021 16:07:39
User entered 'No (N)'	System	04 Mar 2021 16:07:39

US3832074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:03:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:27:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E17EA7C4-9620-462C-A86D-EB679206869E)', Time: '2021-03-04T11:07:35-05:00', User OID: 'PatientReportedOutcome (US3832074)', ODM File OID: 'd3ba7bbf-2f8e-4da9-ab0c-50d813ee4244'	System	04 Mar 2021 16:07:39
User entered '04 Mar 2021 11:07:35'	System	04 Mar 2021 16:07:39

US3832074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	30 Oct 2020 14:50:50

US3832074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '30 Oct 2020'	Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:50:50
	(b) (4)	

US3832074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:50:50

US3832074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:50:50

US3832074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	30 Oct 2020 14:50:54

US3832074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:49:12
User entered 'I'	System	30 Oct 2020 14:50:54

US3832074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Nov 2020 20:07:25

US3832074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '30 Nov 2020'	Alyssa-Kay Peay (b) (4)	30 Nov 2020 20:07:25
	(b) (4)	

US3832074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	30 Nov 2020 20:07:25

US3832074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Nov 2020 20:07:25

US3832074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Nov 2020 20:07:29

US3832074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User entered 'I'	System	30 Nov 2020 20:07:29

US3832074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	30 Dec 2020 18:47:41

US3832074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '30 Dec 2020'	Emma Partin (b) (4)	30 Dec 2020 18:47:41

US3832074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	30 Dec 2020 18:47:41

US3832074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	30 Dec 2020 18:47:41

US3832074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	30 Dec 2020 18:47:28

US3832074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User entered 'I'	System	30 Dec 2020 18:47:28

US3832074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	01 Feb 2021 15:40:13

US3832074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '1 Feb 2021'	Rodolfo Barrera (b) (4)	01 Feb 2021 15:40:13

US3832074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	01 Feb 2021 15:40:13

US3832074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Rodolfo Barrera (b) (4)	01 Feb 2021 15:40:13

US3832074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	01 Feb 2021 15:40:18

US3832074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:31:07
User entered 'I'	System	01 Feb 2021 15:40:18

US3832074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:22
User entered 'Yes (Y)'	Emma Partin (b) (4)	22 Feb 2021 18:10:09

US3832074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:22
User entered '22 Feb 2021'	(b) (4)	
	Emma Partin (b) (4)	22 Feb 2021 18:10:09
	(b) (4)	

US3832074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:22
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	22 Feb 2021 18:10:09

US3832074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered 'VISIT4'	System	22 Feb 2021 18:10:09

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered 'No (N)'	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered empty.	System	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered empty.	System	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24
	(b) (4)	

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered empty.	System	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered empty.	System	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered empty.	System	31 Mar 2021 12:28:24

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39

US3832074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39

US3832074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	Emma Partin (b) (4)	22 Feb 2021 18:10:16

US3832074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	Emma Partin (b) (4)	22 Feb 2021 18:10:16

US3832074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	01 Mar 2021 17:37:01

US3832074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	Rodolfo Barrera (b) (4)	01 Mar 2021 17:37:01

US3832074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '10:13'	Rodolfo Barrera (b) (4)	01 Mar 2021 17:37:01

US3832074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered '22 Feb 2021 10:13'	System	01 Mar 2021 17:37:01

US3832074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	Emma Partin (b) (4)	22 Feb 2021 18:10:18

US3832074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:39
User entered 'I'	System	22 Feb 2021 18:10:18

US3832074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	30 Mar 2021 18:41:10
	(b) (4)	

US3832074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
	(b) (4)	
User entered '30 Mar 2021'	Rodolfo Barrera (b) (4)	30 Mar 2021 18:41:10
	(b) (4)	

US3832074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	30 Mar 2021 18:41:10

US3832074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	30 Mar 2021 18:41:10
	(b) (4)	

US3832074

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	30 Mar 2021 18:41:15
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:41:15

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Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	29 Apr 2021 17:10:29
	(b) (4)	

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Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered '29 Apr 2021'	Rodolfo Barrera (b) (4)	29 Apr 2021 17:10:29
	(b) (4)	

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Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	29 Apr 2021 17:10:29
	(b) (4)	

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Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	29 Apr 2021 17:10:29
	(b) (4)	

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Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:37
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	29 Apr 2021 17:10:34
	(b) (4)	

US3832074

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 17:10:34

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 17:56:20

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 17:56:20

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	05 Jan 2021 17:56:20

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 17:56:20

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:21:49

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 18:53:13
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4)	08 Apr 2021 20:08:23
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 20:08:16
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:40:35
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:21:49

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:10:26
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	05 Jan 2021 17:58:37
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	Alyssa-Kay Peay (b) (4)	10 Feb 2021 14:53:10
User entered 'Placebo (Placebo)'	(b) (4)	
	System	20 Jan 2021 06:10:26
	Emma Partin (b) (4)	05 Jan 2021 17:58:37
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'I'	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:03:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'I'	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '66.0' in	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '181.0' lb	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '29.27525'	System	05 Jan 2021 18:00:24
DataPoint set to visible.	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '66.0' in	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '181.0' lb	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '29.27525'	System	05 Jan 2021 18:00:24
DataPoint set to visible.	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '12:04'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '5 Jan 2021 12:04'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '97.8' F	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Oral (Oral)'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '94'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'bpm'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '12'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'breaths/min'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '137'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'mmHg'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '73'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'mmHg'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '66.0' in	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '181.0' lb	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:03:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '29.27525'	System	05 Jan 2021 18:00:24
DataPoint set to visible.	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '12:45'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '5 Jan 2021 12:45'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '98.2' F	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Oral (Oral)'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '82'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'bpm'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '16'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'breaths/min'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '130'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'mmHg'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '76'	Emma Partin (b) (4)	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'mmHg'	System	05 Jan 2021 18:00:24

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 18:00:31

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 18:00:31

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'mRNA-1273'	System	05 Jan 2021 18:00:51
DataPoint set to visible.	System	05 Jan 2021 17:58:37

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '12:14'	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '5 Jan 2021 12:14'	System	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'ONCE'	System	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 18:00:51

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 17:57:29

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 17:57:29

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '11:57'	Emma Partin (b) (4)	05 Jan 2021 17:57:29

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '5 Jan 2021 11:57'	System	05 Jan 2021 17:57:29

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 17:58:23

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:19

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '5 Jan 2021'	Emma Partin (b) (4)	05 Jan 2021 17:58:23

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '11:53'	Emma Partin (b) (4)	05 Jan 2021 17:58:23

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:03:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered '5 Jan 2021 11:53'	System	05 Jan 2021 17:58:23

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	Emma Partin (b) (4)	05 Jan 2021 18:01:39

US3832074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:44:26
User entered 'I'	System	05 Jan 2021 18:01:39

US3832074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Jan 2021 17:21:37
	(b) (4)	

US3832074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '13 Jan 2021'	Emma Partin (b) (4)	20 Jan 2021 17:21:37
	(b) (4)	

US3832074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	20 Jan 2021 17:21:37
	(b) (4)	

US3832074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Emma Partin (b) (4)	20 Jan 2021 17:21:37
	(b) (4)	

US3832074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Jan 2021 17:21:41
	(b) (4)	

US3832074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User entered 'I'	System	20 Jan 2021 17:21:41

US3832074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:25
User entered 'I'	System	20 Jan 2021 17:21:41
DataPoint set to visible.	System	20 Jan 2021 17:21:41

US3832074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:10:29

US3832074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 10:55:52
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'Data is correct as reported and will be noted as PD' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:59:16
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Feb 2021 18:10:29
User entered '22 Feb 2021'	Emma Partin (b) (4) (b) (4)	22 Feb 2021 18:10:29

US3832074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	22 Feb 2021 18:10:29

US3832074

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'OLD29'	System	22 Feb 2021 18:10:29

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '10:25'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered '22 Feb 2021 10:25'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '97.9' F	Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered empty.	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '73'	Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'bpm'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '13'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'breaths/min'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '119'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'mmHg'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '71'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'mmHg'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '11:02'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered '22 Feb 2021 11:02'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '98.0' F	Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered empty.	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '62'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'bpm'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '13'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'breaths/min'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '126'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'mmHg'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '70'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:03:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'mmHg'	System	22 Feb 2021 18:12:41

US3832074

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:10:44

US3832074

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:10:44

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered empty.	Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered empty.	Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'mRNA-1273'	System	03 Mar 2021 15:51:31
DataPoint set to visible.	System	20 Jan 2021 17:21:41

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '22 Feb 2021'	(b) (4) Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered '10:31'	(b) (4) Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered '22 Feb 2021 10:31'	System	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Left Arm (LEFT ARM)'	Rodolfo Barrera (b) (4)	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'ONCE'	System	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:03:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 15:51:31

US3832074

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:07:12
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	22 Feb 2021 18:12:48

US3832074

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:50:37
User entered 'I'	System	22 Feb 2021 18:12:48

US3832074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Mar 2021 14:30:54
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Mar 2021 14:29:44

US3832074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty; reason for change Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	12 Mar 2021 14:30:54
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	12 Mar 2021 14:30:28
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	12 Mar 2021 14:30:28
User entered '01 Mar 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Mar 2021 14:30:28
	(b) (4)	
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 14:29:44
User entered '11 Feb 2021'	Danyel Johnson (b) (4)	12 Mar 2021 14:29:44
	(b) (4)	

US3832074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Mar 2021 14:30:54
User entered 'Contact Made (CONTACT MADE)'	Danyel Johnson (b) (4)	12 Mar 2021 14:29:44

US3832074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:03:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered empty.	Danyel Johnson (b) (4)	12 Mar 2021 14:29:44

US3832074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:03:25
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Mar 2021 14:31:00

US3832074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:03:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:50
User entered 'I'	System	12 Mar 2021 14:31:00

US3832074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Apr 2021 19:33:14

US3832074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered '25 Mar 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 19:34:48
User entered '29 Mar 2021'	Danyel Johnson (b) (4)	14 Apr 2021 19:33:14

US3832074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	14 Apr 2021 19:33:14

US3832074

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:03:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered 'OLD57'	System	14 Apr 2021 19:33:14

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered empty.	System	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered empty.	System	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered empty.	System	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered empty.	System	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered empty.	System	14 Apr 2021 19:33:57

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52

US3832074

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:03:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52

US3832074

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Apr 2021 19:34:08

US3832074

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:03:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered empty.	Danyel Johnson (b) (4)	14 Apr 2021 19:34:08

US3832074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Apr 2021 19:34:34

US3832074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	14 Apr 2021 19:34:48
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	14 Apr 2021 19:34:48
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Apr 2021 19:34:34
User entered '25 Mar 2021'	Danyel Johnson (b) (4)	14 Apr 2021 19:34:34
	(b) (4)	

US3832074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User entered '10:15'	Danyel Johnson (b) (4)	14 Apr 2021 19:34:34

US3832074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:03:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:47:52
User entered '25 Mar 2021 10:15'	System	14 Apr 2021 19:34:34

US3832074

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:03:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:22:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:19:30

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:11
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:45:07

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 04:03:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 04:03:31
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 20:14:19
Coding entries removed.	Danyel Johnson (b) (4)	13 Oct 2020 20:13:24
	(b) (4)	
User entered 'ST Elevation Myocardial Infarction (unspecified artery)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:13:24
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:27:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:27:35
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 17:26:28
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User closed query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid as the subject confirmed using them on a as needed bases. If the dates are unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:40:44
Query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid as the subject confirmed using them on a as needed bases. If the dates are unknown, please state so. ' answered with 'Please see log lines 11/12' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 17:02:44
User opened query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid as the subject confirmed using them on a as needed bases. If the dates are unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 22:28:35
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 20:14:41
User entered empty; reason for change New Information	Danyel Johnson (b) (4)	13 Oct 2020 20:14:41
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 20:13:24
User entered '23:34' reason for change: New Information	Danyel Johnson (b) (4)	13 Oct 2020 20:13:24
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:14:41
User entered '16 Sep 2020 23:34'	System	13 Oct 2020 20:13:24
User entered empty.	System	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:13:24
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 06:38:40
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:30:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Updated' (Site from System).	Danyel Johnson (b) (4)	13 Oct 2020 20:14:28
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Danyel Johnson (b) (4)	13 Oct 2020 20:14:00
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 20:13:24
User entered '18 Sep 2020' reason for change: New Information	Danyel Johnson (b) (4)	13 Oct 2020 20:13:24
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)	28 Sep 2020 15:11:30
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'Per CDM: Site response noted, Please complete Hospital Discharge Date when available and route back to DM.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:38:46
Query 'Per CDM: Site response noted, Please complete Hospital Discharge Date when available and route back to DM.' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	13 Oct 2020 20:14:26
	(b) (4)	
User opened query 'Per CDM: Site response noted, Please complete Hospital Discharge Date when available and route back to DM.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:30:01
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 10:27:53
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Discharge date not entered as subject is currently hospitalized. Will update upon discharge.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 17:26:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 17:25:52
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:31:04
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Data updated' (Site from Safety).	Danyel Johnson (b) (4)	13 Oct 2020 20:14:55
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	13 Oct 2020 20:13:24
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:10:26
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

US3832074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:03:19

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'PV Query: Please update action taken with study drug to not applicable since subject had already declined second dose of study drug prior to event onset, and would no longer be getting any additional doses.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:00:11
Query 'PV Query: Please update action taken with study drug to not applicable since subject had already declined second dose of study drug prior to event onset, and would no longer be getting any additional doses.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	09 Feb 2021 19:08:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 19:07:31
User opened query 'PV Query: Please update action taken with study drug to not applicable since subject had already declined second dose of study drug prior to event onset, and would no longer be getting any additional doses.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:44:06
User closed query 'Per DM CLR - RQ: Site's response noted. However, if this AE is not the reason for Dose Discontinuation, then this should NOT be recorded as "Investigational Product Withdrawn". Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:19:47
Query 'Per DM CLR - RQ: Site's response noted. However, if this AE is not the reason for Dose Discontinuation, then this should NOT be recorded as "Investigational Product Withdrawn". Review and update. Else, clarify. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	26 Jan 2021 20:39:03
User entered 'None (NONE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Jan 2021 20:38:42
User opened query 'Per DM CLR - RQ: Site's response noted. However, if this AE is not the reason for Dose Discontinuation, then this should NOT be recorded as "Investigational Product Withdrawn". Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:29:07

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
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)	10 Dec 2020 05:52:57
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)	04 Dec 2020 20:40:51
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 per query ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 17:06:39
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 'Subject did not discontinue due to AE but, secondary to being uneasy about receive vaccine ' (Site from System).	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 17:06:21
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	03 Dec 2020 17:03:28
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 17:03:28
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 17:03:28
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)	02 Dec 2020 22:26:44
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:39:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Data updated' (Site from DM).	Danyel Johnson (b) (4)	13 Oct 2020 20:15:06
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:52:54
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:39:59
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	Danyel Johnson (b) (4)	13 Oct 2020 20:15:23
answered with 'Data updated ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:52:59
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:22:25
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)	14 Oct 2020 13:31:16
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).	Danyel Johnson (b) (4)	13 Oct 2020 20:15:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Danyel Johnson (b) (4)	13 Oct 2020 20:15:44
Data Entry Error	(b) (4)	
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)	28 Sep 2020 15:12:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'PV Query: Please provide any laboratory or diagnostic tests used to diagnose the MI (EKG, troponin, CK/MB, cardiac cath, etc.). If unable to fit in narrative, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). Query 'PV Query: Please provide any laboratory or diagnostic tests used to diagnose the MI (EKG, troponin, CK/MB, cardiac cath, etc.). If unable to fit in narrative, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Obtained medical records sent' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:00:33
User opened query 'PV Query: Please provide any laboratory or diagnostic tests used to diagnose the MI (EKG, troponin, CK/MB, cardiac cath, etc.). If unable to fit in narrative, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.'	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 19:08:34
User closed query 'PV Query: Thank you for confirming the subject did not take Pepcid or Benadryl. Please remove those from the concomitant medications, thanks!' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:44:48
Query 'PV Query: Thank you for confirming the subject did not take Pepcid or Benadryl. Please remove those from the concomitant medications, thanks!' answered with 'Spoke with subject again about use of Pepcid and Benadryl after reviewing the generic name of these medications subject confirms using them on a as needed bases ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:30:57
User opened query 'PV Query: Thank you for confirming the subject did not take Pepcid or Benadryl. Please remove those from the concomitant medications, thanks!' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	23 Nov 2020 16:29:16
User closed query 'PV Query: Thank you for confirming the subject did not take Pepcid or Benadryl. Please remove those from the concomitant medications, thanks!' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:15:55

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:11:41
Query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid. If unknown, please state so.' answered with 'On review with subject, subject denies use of Pepcid or Benadryl ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:55:35
User opened query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:47:58
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:22:25
User closed query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:24:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:24:40
User closed query 'PV Query: Please report why the subject did not receive the second dose of study medication. ' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 21:56:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'No noted relevant labs all labs obtained wnl. diagnostic test updated' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:00:52
Query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 11:59:58
Query 'PV Query: Please report why the subject did not receive the second dose of study medication. ' answered with 'Subject Decision ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	21 Oct 2020 21:11:43
User opened query 'PV Query: Please provide start date for concomitant medication of Benadryl and Pepcid' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:14:09

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:14:00
User opened query 'PV Query: Please report why the subject did not receive the second dose of study medication. ' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:13:52
User closed query 'PV Query: Please report why the subject did not receive the second dose of study medication.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:31:32
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)	14 Oct 2020 13:31:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:31:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'AT DAY 43 SAFETY CALL, SUBJECT REPORTED CURRENT HOSPITAL ADMISSION DUE TO MYOCARDIAL INFARCTION. SUBJECT STATES SHE WAS ADMITTED ON 16SEP2020 AND WAS TOLD SHE WOULD LIKELY BE DISCHARGED ON 19SEP2020. SUBJECT REPORTS RECEIVING MEDICATIONS DURING ADMISSION BUT UNABLE TO RECALL THE NAMES/DOSES AT THIS TIME. SUBJECT REPORTS HAVING PROCEDURE PERFORMED, BUT CANNOT RECALL NAME. SUBJECT INSTRUCTED TO CONTACT OFFICE FOR MEDICAL RECORD RELEASE AUTHORIZATION UPON DISCHARGE. SUBJECT VERBALIZED UNDERSTANDING. WILL UPDATE UPON RECEIPT AND REVIEW OF MEDICAL RECORDS. UPDATED 06/10/2020 EVENT TERM UPDATED TO ST ELEVATION MYOCARDIAL INFARCTION (UNSPECIFIED ARTERY) Unclear if primary cardiac event V's Uncontrolled Hypertension PROCEDURES, CONCOMITANT MEDICATIONS, AND LABS OBTAINED UPDATED AS PER MEDICAL RECORD REVIEW' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:27:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'AT DAY 43 SAFETY CALL, SUBJECT REPORTED CURRENT HOSPITAL ADMISSION DUE TO MYOCARDIAL INFARCTION. SUBJECT STATES SHE WAS ADMITTED ON 16SEP2020 AND WAS TOLD SHE WOULD LIKELY BE DISCHARGED ON 19SEP2020. SUBJECT REPORTS RECEIVING MEDICATIONS DURING ADMISSION BUT UNABLE TO RECALL THE NAMES/DOSES AT THIS TIME. SUBJECT REPORTS HAVING PROCEDURE PERFORMED, BUT CANNOT RECALL NAME. SUBJECT INSTRUCTED TO CONTACT OFFICE FOR MEDICAL RECORD RELEASE AUTHORIZATION UPON DISCHARGE. SUBJECT VERBALIZED UNDERSTANDING. WILL UPDATE UPON RECEIPT AND REVIEW OF MEDICAL RECORDS. Updated: Event term updated to ST Elevation Myocardial Infarction (unspecified Artery), Procedures, Concomitant medications, and Labs obtained updated as per medical record review' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:18:39
Query 'PV Query: Please report why the subject did not receive the second dose of study medication.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	13 Oct 2020 20:16:15
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 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	13 Oct 2020 20:16:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	13 Oct 2020 20:16:02
User opened query 'PV Query: Please report why the subject did not receive the second dose of study medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:13:10

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[Narrative](#)

Audit	User	Time (GMT)
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)	28 Sep 2020 15:12:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:12:19
User entered 'At Day 43 safety call, subject reported current hospital admission due to Myocardial Infarction. Subject states she was admitted on 16Sep2020 and was told she would likely be discharged on 19Sep2020. Subject reports receiving medications during admission but unable to recall the names/doses at this time. Subject reports having procedure performed, but cannot recall name. Subject instructed to contact office for medical record release authorization upon discharge. Subject verbalized understanding. Will update upon receipt and review of medical records.'	(b) (4), (b) (6)	18 Sep 2020 17:25:52

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 17:25:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:25:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:25:52

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4) (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 20:57:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 20:57:08
Data point term sent to Coder	System	13 Apr 2021 20:56:12
User entered 'Right Wrist Fracture'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '15 Mar 2021'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 20:55:00
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4) (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:01:56

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

US3832074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 20:55:00
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4) (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'None (NONE)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '1'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:28
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Apr 2021 20:55:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 20:55:00
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4) (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 20:55:00
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4) (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:03:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Danyel Johnson (b) (4)	13 Apr 2021 20:53:15
DataPoint inactivated with code reason code Data not required.	Danyel Johnson (b) (4)	22 Oct 2020 12:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
User closed query 'Please add AE right wrist fracture start 15Mar2021, ongoing, gr 2 , medically attended ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:10:33
Query 'Please add AE right wrist fracture start 15Mar2021, ongoing, gr 2 , medically attended ' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	13 Apr 2021 20:52:33
User opened query 'Please add AE right wrist fracture start 15Mar2021, ongoing, gr 2 , medically attended ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:40:06
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:43:45
Data point term sent to Coder	System	13 Nov 2020 14:43:00
User entered 'LUMBAR BACK PAIN'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '07 Sep 2020'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
User entered empty.	System	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Generated On: 10 Jun 2021 10:03:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '08 Sep 2020'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
User entered empty.	System	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'None (NONE)'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'I'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
User entered '0'	System	13 Nov 2020 14:42:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17
User entered '0'	System	13 Nov 2020 14:42:11

US3832074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:03:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:03:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:23:11
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 19:59:24

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:25:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:44:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:44:19
Data point term sent to Coder	System	06 Aug 2020 20:00:32
User entered 'Simvastation'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'Hyperlipidemia'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered '20'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:25:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 12:13:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 20:00:05
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:23:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered '16 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:23:54
User entered empty.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:25:28
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User entered '1'	System	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User entered '1'	System	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:12
User entered '804 (804)'	System	06 Aug 2020 20:00:05

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:02:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:02:03
Data point term sent to Coder	System	06 Aug 2020 20:01:33
User entered 'Lisinopril'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'hypertension'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered '20'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 12:13:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 20:00:41
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 20:00:41
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:25:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 20:00:41

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 14:41:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	13 Nov 2020 14:41:44
Data point term sent to Coder Coding entries removed.	System	13 Nov 2020 14:40:59
	Danyel Johnson (b) (4)	13 Nov 2020 14:40:43
DataPoint Verified.	(b) (4)	27 Oct 2020 21:26:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 15:03:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Oct 2020 15:03:14
Data point term sent to Coder User entered 'Aleve'	System	06 Oct 2020 14:30:09
	Emma Partin (b) (4)	06 Oct 2020 14:29:16
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:50:18
(Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	Danyel Johnson (b) (4)	13 Nov 2020 14:40:56
' answered with 'Verified and updated as an AE' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 14:40:43
User entered 'Lumbar back pain' reason for change:	(b) (4)	
Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:40:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4)	
(Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:33:29
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'Back Aches'	Emma Partin (b) (4)	06 Oct 2020 14:29:16
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:04:37
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 18:08:26
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 18:08:12
User entered '220' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 18:08:12
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:26:15
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered '200'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'mg (mg)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'as needed (PRN)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'Oral (ORAL)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered '07 Sep 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered '0'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	10 Dec 2020 23:54:50
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered '08 Sep 2020'	Emma Partin (b) (4)	06 Oct 2020 14:29:16
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:10
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User entered empty.	System	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User entered empty.	System	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:30:19
User entered empty.	System	06 Oct 2020 14:29:16

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 15:47:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 15:47:22
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 14:32:15
User entered 'Nitroglycerin'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'AE - Myocardial Infarction'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered '0.4' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:28:12
	(b) (4)	
User entered '0.'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'mg (mg)'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'as needed (PRN)'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'Other (OTHER)'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'sublingual'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered '17 Sep 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered '0'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:50:23
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'medication will continue on as needed bases' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:51:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:35
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:31:48
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:31:48

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:08:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:08:15
Data point term sent to Coder	System	06 Oct 2020 14:34:19
User entered 'Isosorbide Mononitrate'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'AE - Myocardial Infarction'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered '30'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'mg (mg)'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'once daily (QD)'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'Oral (ORAL)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered '17 Sep 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered '0'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:51:22
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Medication will continue as a result of the AE' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:51:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:34:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:26:55
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:33:21
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:33:21

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:10:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:10:17
Data point term sent to Coder	System	06 Oct 2020 14:34:17
User entered 'Clopidogrel'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'No (N)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'AE - Myocardial Infarction'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered '75'	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'mg (mg)'	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'once daily (QD)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'Oral (ORAL)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered '17 Sep 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered '0'	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:51:30
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'This medication will continue as a result of the AE' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:52:19
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:34:22
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered empty.	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:41:40
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:34:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:34:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:56:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:56:21
Data point term sent to Coder	System	06 Oct 2020 14:35:20
User entered 'Metoprolol Tartrate'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'Myocardial Infarction'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered '25'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'mg (mg)'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'twice daily (BID)'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'Oral (ORAL)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered empty.	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered '17 Sep 2020'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered '0'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:51:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'This medication will continue as a result of the AE' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:52:50
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:34:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered empty.	Emma Partin (b) (4) (b) (4)	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:29:45
User entered 'No (N)'	Emma Partin (b) (4)	06 Oct 2020 14:34:57
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:34:57

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:26:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:26:21
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 20:25:38
User entered 'crestor'	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'No (N)'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'Dyslipidemia'	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered '20'	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'mg (mg)'	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered empty.		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'once daily (QD)'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'Oral (ORAL)'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered empty.		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered '19 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:25:23

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered '0'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:25:23
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:44:45
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:25:23

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:25:23

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:25:23

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:25:23

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:35:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:35:16
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 20:33:54
User entered 'Aspirin'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'Cardiac Prophylaxis'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered '81'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'mg (mg)'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered empty.		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'once daily (QD)'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered empty.		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'Oral (ORAL)'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered empty.		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered '19 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:33:33

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered '0'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered empty.	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:33:33

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:40:27
User entered 'No (N)'		
	Danyel Johnson (b) (4)	13 Oct 2020 20:33:33
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:33:33

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:33:33

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:33:33

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Oct 2020 20:38:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:38:50
Data point term sent to Coder	System	13 Oct 2020 20:37:05
User entered 'Benadryl'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:56:43
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:53:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Reviewed and updated per subject report' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:57:03
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:35:14
User entered 'Sleep Aid'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '25'	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'mg (mg)'	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'as needed (PRN)'	(b) (4) Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Nov 2020 15:12:27
User entered 'un UNK 2010' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 15:12:27
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Nov 2020 15:12:19
User entered ' 2010' (non-conformant).	Danyel Johnson (b) (4)	13 Nov 2020 15:12:19
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:13:09
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 15:13:09
	(b) (4)	
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	13 Nov 2020 15:12:27
User entered '1'	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 20:37:02
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Oct 2020 20:37:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:36:55
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:36:55
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:36:55

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Feb 2021 14:38:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:38:47
Data point term sent to Coder	System	10 Feb 2021 14:37:42
User closed query 'CDM-Coding: This medication can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. '(Site from System).	System	10 Feb 2021 14:37:33
Query 'CDM-Coding: This medication can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'updated' (Site from System).	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 14:37:33
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 14:37:27
User entered 'PEPCID (Famotidine)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 14:37:27
User opened query 'CDM-Coding: This medication can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. '(Site from System).	Coder Import (b) (4) (b) (4)	10 Feb 2021 02:26:00

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:39:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:39:17
Data point term sent to Coder	System	13 Oct 2020 20:38:06
User entered 'Pepcid'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 15:14:58
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:23:25
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated per subject report' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 15:15:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:36:05
User entered 'Acid Reflux'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:37:59

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '20'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'mg (mg)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '1'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	13 Oct 2020 20:37:59
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:37:59

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:37:59

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:37:59

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
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.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 05:50:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:50:50
Data point term sent to Coder	System	29 Oct 2020 18:30:17
User entered 'Rosuvastatin'	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Adverse Event - Myocardial Infarction'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '20'	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'mg (mg)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '17 Sep 2020'	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02
	(b) (4)	

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '0'	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:04:58
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Data is correct as reported medication will remain ongoing' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 18:09:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 06:27:01
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:03:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 18:30:02

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:03:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:53:30
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	13 Oct 2020 20:18:53

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '16 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:19:43

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Chest X-Ray'	Danyel Johnson (b) (4)	13 Oct 2020 20:19:43
	(b) (4)	

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	13 Oct 2020 20:19:43
	(b) (4)	

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:03:19

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:19:43
	(b) (4)	

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '16 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:20:30

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'LCH- Attempted PCI to RCA Unsuccessful'	Danyel Johnson (b) (4)	13 Oct 2020 20:20:30

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	13 Oct 2020 20:20:30

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:03:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:20:30

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:03:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '16 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:21:57

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Cardiac echo: noted low normal left ventricle systolic function, Grade 1 left ventricular diastolic dysfunction'	Danyel Johnson (b) (4)	13 Oct 2020 20:21:57

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	13 Oct 2020 20:21:57

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:03:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:21:57

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:03:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '16 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	13 Oct 2020 20:22:58

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Labs obtained all noted within normal limits with the exception of glucose noted at 144'	(b) (4) Danyel Johnson (b) (4)	13 Oct 2020 20:22:58

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	13 Oct 2020 20:22:58

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:03:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	13 Oct 2020 20:22:58

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:03:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	10 Dec 2020 23:54:50
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	10 Dec 2020 19:56:01
User entered '17 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:58:48

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:03:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Heart Catherization'	(b) (4) Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:58:48

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:03:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Per DM CLR: Indication = Medical History, however, the possible corresponding medical condition is recorded in the AE eCRF. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 05:54:17
Query 'Per DM CLR: Indication = Medical History, however, the possible corresponding medical condition is recorded in the AE eCRF. Please review and update as appropriate, otherwise clarify.'	Danyel Johnson (b) (4) (b) (4)	07 Dec 2020 15:05:13
answered with 'Updated per review' (Site from DM).		
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	07 Dec 2020 15:05:01
User opened query 'Per DM CLR: Indication = Medical History, however, the possible corresponding medical condition is recorded in the AE eCRF. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:56:30
User entered 'Medical History (MH)'	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:58:48

US3832074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:03:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:38:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:58:48

US3832074

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:03:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '4 Sep 2020'	(b) (4)	16 Sep 2020 12:04:47
	(b) (4), (b) (6)	

US3832074

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:03:19

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Other (OTHER)'	(b) (4)	16 Sep 2020 12:04:47
	(b) (4), (b) (6)	

US3832074

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:03:19

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'Subject did not withdraw consent for the study, but did not wish to receive second IP dose. Subject agreed to continue study participation with all other procedures/assessments per protocol.'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:04:47

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 08:15:24
Query 'Data is required. Please complete.' answered with 'subject withheld treatment but agreed to remain in the study to collect safety data' (Site from System).	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 23:55:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 23:54:50
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 23:54:50
User entered '04 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 08:15:26
Query 'Data is required. Please complete.' answered with 'Subject withdrew from treatment but, agreed to stay in to collect safety data' (Site from System).	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 23:56:10
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 23:54:50
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 23:54:50
User entered 'Other (OTHER)'	Danyel Johnson (b) (4) (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	10 Dec 2020 23:54:50
User entered 'Due to personal reasons subject wished to withdrawal from treatment but, remain in the study'	Danyel Johnson (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:03:19

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered empty.	Danyel Johnson (b) (4)	10 Dec 2020 19:56:01

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered		
'USA-US100-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-MRNA-1273-P301000002'		

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
User entered '20/Sep/2020 13:45'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-MRNA-1273-P301000002'		

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
User entered '14/Oct/2020 13:32'	System	14 Oct 2020 13:32:10

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 21:57:12
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 13:32:10

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered		
'USA-US100-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
User entered '22/Oct/2020 17:57'	System	22 Oct 2020 21:57:27

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 15:25:33
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 21:57:27

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-MRNA-1273-P301000002'		

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
User entered '23/Oct/2020 15:25'	System	23 Oct 2020 15:25:43

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 15:25:51
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 15:25:43

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-MRNA-1273-P301000002'		

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:08:35
User entered '12/Nov/2020 22:11'	System	12 Nov 2020 22:11:56

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:08:37
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 20:28:43
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 22:11:56

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered	System	20 Sep 2020 17:45:07
'USA-US100-2020-MRNA-1273-P301000002'		

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:09:40
User entered '04/Dec/2020 20:40'	System	04 Dec 2020 20:40:14

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:35:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:09:41
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 20:40:14

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered		
'USA-US100-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:19:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '27/Jan/2021 08:36'	(b) (4) System	27 Jan 2021 13:36:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:03:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:19:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 16:25:12
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 13:36:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered		
'USA-US100-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

US3832074

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Yes (Y)'	System	20 Sep 2020 17:45:07

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Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'No (N)'	System	20 Sep 2020 17:45:07

US3832074

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Gowdhami'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Mohan'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'Anderson'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered 'SC'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:45:27
User entered '29621'	System	20 Sep 2020 17:45:07

US3832074

Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 21:19:46
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:31:55
User entered 'US'	System	20 Sep 2020 17:45:36

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:03:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
	(b) (4)	
User entered '8'	System	10 Feb 2021 16:25:33
User entered '7'	System	27 Jan 2021 13:36:07
User entered '6'	System	04 Dec 2020 20:40:14
User entered '5'	System	12 Nov 2020 22:11:56
User entered '4'	System	23 Oct 2020 15:25:43
User entered '3'	System	22 Oct 2020 21:57:27
User entered '2'	System	14 Oct 2020 13:32:10
User entered '1'	System	20 Sep 2020 17:45:36

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Folder: SAE USA-US100-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:03:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:19:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered '10/Feb/2021 10:25'	(b) (4) System	10 Feb 2021 16:25:33

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Form: Safety Report Form (9)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:19:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:01:25
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:25:33