

US3752366 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

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US3752366

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 19:43:30

Generated On: 12 Aug 2021 13:21:23

[Participant ID](#)

US3752366

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

US3752366

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SCRN

US3752366

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:43:33

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Date of Informed Consent (*dd MMM yyyy*) 02 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" 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) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Condition	ALLERGIC CONJUNCTIVITIS
Start date (dd MMM yyyy)	UN UNK 1990
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Condition	DECOMPRESSION LEFT SUBACROMIAL ARTHROSCOPY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Condition	GRADE I CARDIAC MURMUR (FINAL DIAGNOSIS UNKNOWN)
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:28 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:28
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	251 lb
BMI (<i>xxx.x</i>)	35.08059 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:34

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:43:37

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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) 12 Feb 2021 19:43:37

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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) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 111046

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

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) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	13:28 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:28
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)	112 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) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 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: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 02 SEP 2020

What was the treatment time? (00:00-23:59) 14:18 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 14:18

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) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

02 SEP 2020 13:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:38	02 SEP 2020 13:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:37

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 14:45

PC Open Date & Time

02 SEP 2020 14:38

PC Close Date & Time

02 SEP 2020 17:08

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	02 SEP 2020 21:40
PC Open Date & Time	02 SEP 2020 18:03
PC Close Date & Time	03 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

101.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 19:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 SEP 2020 22:15

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:57

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 14:46

PC Open Date & Time

02 SEP 2020 14:38

PC Close Date & Time

02 SEP 2020 17:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:40

PC Open Date & Time

02 SEP 2020 18:03

PC Close Date & Time

03 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:37

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 19:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:15

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:57

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 14:46
PC Open Date & Time	02 SEP 2020 14:38
PC Close Date & Time	02 SEP 2020 17:08

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 21:41
PC Open Date & Time	02 SEP 2020 18:03
PC Close Date & Time	03 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:00
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:37

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 16:37
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3752366

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

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

Visit date (dd MMM yyyy)	07 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:20
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

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	

US3752366

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

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?

US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

13:47 (24 HR)

Collection date and time (derived)

07 OCT 2020 13:47

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	07 OCT 2020 13:52
Nasopharyngeal Swab 2	No		

US3752366

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:39:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 12:40
Temperature (xxx.x)	98.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752366

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3752366

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 NOV 2020

Collection time (00:00-23:59)

12:52 (24 HR)

Collection date and time (derived)

04 NOV 2020 12:52

US3752366

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:38

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 64

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

No ☒

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 NOV 2020 00:13:25

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 06:43:30

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 07:50:46

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 09:33:24
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:20:06
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 11:51:32

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 11:48:34

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 06:51:44

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:10:55

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 11:14:10

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 12:17:07
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 07:00:48
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 12:08:57

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 06:49:29
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 06:51:21

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 23:34:14

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 18:31:43

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 15:30:52

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 MAY 2021 00:01

Patient Cloud Close Date & Time

11 MAY 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 MAY 2021 00:01

Patient Cloud Close Date & Time

18 MAY 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 MAY 2021 00:01

Patient Cloud Close Date & Time

25 MAY 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 MAY 2021 00:01

Patient Cloud Close Date & Time

01 JUN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 JUN 2021 00:01

Patient Cloud Close Date & Time

08 JUN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 JUN 2021 00:01

Patient Cloud Close Date & Time

15 JUN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 JUN 2021 00:01

Patient Cloud Close Date & Time

22 JUN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JUN 2021 00:01

Patient Cloud Close Date & Time

29 JUN 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JUL 2021 00:01

Patient Cloud Close Date & Time

06 JUL 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JUL 2021 00:01

Patient Cloud Close Date & Time

13 JUL 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JUL 2021 00:01

Patient Cloud Close Date & Time

20 JUL 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JUL 2021 00:01

Patient Cloud Close Date & Time

27 JUL 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUL 2021 00:01

Patient Cloud Close Date & Time

03 AUG 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 AUG 2021 00:01

Patient Cloud Close Date & Time

10 AUG 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 AUG 2021 00:01

Patient Cloud Close Date & Time

17 AUG 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 AUG 2021 00:01

Patient Cloud Close Date & Time

24 AUG 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 AUG 2021 00:01

Patient Cloud Close Date & Time

31 AUG 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 SEP 2021 00:01

Patient Cloud Close Date & Time

07 SEP 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 SEP 2021 00:01

Patient Cloud Close Date & Time

14 SEP 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 SEP 2021 00:01

Patient Cloud Close Date & Time

21 SEP 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 SEP 2021 00:01

Patient Cloud Close Date & Time

28 SEP 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 OCT 2021 00:01

Patient Cloud Close Date & Time

05 OCT 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2021 00:01

Patient Cloud Close Date & Time

12 OCT 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 OCT 2021 00:01

Patient Cloud Close Date & Time

19 OCT 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2021 00:01

Patient Cloud Close Date & Time

26 OCT 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 OCT 2021 00:01

Patient Cloud Close Date & Time

02 NOV 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2021 00:01

Patient Cloud Close Date & Time

09 NOV 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 NOV 2021 00:01

Patient Cloud Close Date & Time

16 NOV 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2021 00:01

Patient Cloud Close Date & Time

23 NOV 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 NOV 2021 00:01

Patient Cloud Close Date & Time

30 NOV 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 DEC 2021 00:01

Patient Cloud Close Date & Time

07 DEC 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 DEC 2021 00:01

Patient Cloud Close Date & Time

14 DEC 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 DEC 2021 00:01

Patient Cloud Close Date & Time

21 DEC 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 DEC 2021 00:01

Patient Cloud Close Date & Time

28 DEC 2021 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 DEC 2021 00:01

Patient Cloud Close Date & Time

04 JAN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JAN 2022 00:01

Patient Cloud Close Date & Time

11 JAN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JAN 2022 00:01

Patient Cloud Close Date & Time

18 JAN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JAN 2022 00:01

Patient Cloud Close Date & Time

25 JAN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JAN 2022 00:01

Patient Cloud Close Date & Time

01 FEB 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 FEB 2022 00:01

Patient Cloud Close Date & Time

08 FEB 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 FEB 2022 00:01

Patient Cloud Close Date & Time

15 FEB 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 FEB 2022 00:01

Patient Cloud Close Date & Time

22 FEB 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 FEB 2022 00:01

Patient Cloud Close Date & Time

01 MAR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 MAR 2022 00:01

Patient Cloud Close Date & Time

08 MAR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 MAR 2022 00:01

Patient Cloud Close Date & Time

15 MAR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 MAR 2022 00:01

Patient Cloud Close Date & Time

22 MAR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 MAR 2022 00:01

Patient Cloud Close Date & Time

29 MAR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 APR 2022 00:01

Patient Cloud Close Date & Time

05 APR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 APR 2022 00:01

Patient Cloud Close Date & Time

12 APR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 APR 2022 00:01

Patient Cloud Close Date & Time

19 APR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 APR 2022 00:01

Patient Cloud Close Date & Time

26 APR 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 APR 2022 00:01

Patient Cloud Close Date & Time

03 MAY 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 MAY 2022 00:01

Patient Cloud Close Date & Time

10 MAY 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 MAY 2022 00:01

Patient Cloud Close Date & Time

17 MAY 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 MAY 2022 00:01

Patient Cloud Close Date & Time

24 MAY 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 MAY 2022 00:01

Patient Cloud Close Date & Time

31 MAY 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUN 2022 00:01

Patient Cloud Close Date & Time

07 JUN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 JUN 2022 00:01

Patient Cloud Close Date & Time

14 JUN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 JUN 2022 00:01

Patient Cloud Close Date & Time

21 JUN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 JUN 2022 00:01

Patient Cloud Close Date & Time

28 JUN 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 JUL 2022 00:01

Patient Cloud Close Date & Time

05 JUL 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 JUL 2022 00:01

Patient Cloud Close Date & Time

12 JUL 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 JUL 2022 00:01

Patient Cloud Close Date & Time

19 JUL 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 JUL 2022 00:01

Patient Cloud Close Date & Time

26 JUL 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 JUL 2022 00:01

Patient Cloud Close Date & Time

02 AUG 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 AUG 2022 00:01

Patient Cloud Close Date & Time

09 AUG 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 AUG 2022 00:01

Patient Cloud Close Date & Time

16 AUG 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 AUG 2022 00:01

Patient Cloud Close Date & Time

23 AUG 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 AUG 2022 00:01

Patient Cloud Close Date & Time

30 AUG 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 SEP 2022 00:01

Patient Cloud Close Date & Time

06 SEP 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 SEP 2022 00:01

Patient Cloud Close Date & Time

13 SEP 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 SEP 2022 00:01

Patient Cloud Close Date & Time

20 SEP 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 SEP 2022 00:01

Patient Cloud Close Date & Time

27 SEP 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 SEP 2022 00:01

Patient Cloud Close Date & Time

04 OCT 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2022 00:01

Patient Cloud Close Date & Time

11 OCT 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2022 00:01

Patient Cloud Close Date & Time

18 OCT 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2022 00:01

Patient Cloud Close Date & Time

25 OCT 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2022 00:01

Patient Cloud Close Date & Time

01 NOV 2022 23:59

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2022 00:01

Patient Cloud Close Date & Time

08 NOV 2022 23:59

US3752366

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:21:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 06:54:14

US3752366

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

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

Visit date (dd MMM yyyy)	07 APR 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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US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 APR 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 12:50
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752366

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 APR 2021

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

US3752366

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

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

Collection date (dd MMM yyyy)	07 APR 2021
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Collection time (00:00-23:59)	12:55 (24 HR)
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Collection date and time (derived)	07 APR 2021 12:55
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US3752366

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Date of Contact	6 SEP 2020
Time of Contact	17:45
Date and Time of Contact (derived)	6 SEP 2020 17:45
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

298 of 4537

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Symptom Day

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

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

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

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 14:52:34

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Date of Visit	8 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	8 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 16:25:04

Generated On: 12 Aug 2021 13:21:23

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 19:43:32

Generated On: 12 Aug 2021 13:21:23

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 SEP 2020
Day 5	Yes	12 SEP 2020
Day 7	Yes	14 SEP 2020
Day 9	Yes	16 SEP 2020
Day 14	Yes	21 SEP 2020
Day 21	Yes	28 SEP 2020
Day 28	Yes	7 OCT 2020

US3752366

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:32

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	SICKD1

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:20
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>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	100 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752366

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:32

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3752366

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 19:43:32

Generated On: 12 Aug 2021 13:21:23

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 SEP 2020

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	SICKD28

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:20
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3752366

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

US3752366

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3752366

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3752366

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Height	180.3 cm
Weight	112.2 kg
BMI (xxx.x)	34.51449

US3752366

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Height	180.3 cm
Weight	112.2 kg
BMI (xxx.x)	34.51449
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:19
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752366

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Height	180.3 cm
Weight	112.2 kg
BMI (xxx.x)	34.51449
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)	14 JAN 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:10
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3752366

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3752366

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 12:40 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 12:40

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

US3752366

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

14 JAN 2021 12:25

US3752366

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

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

Collection date (dd MMM yyyy)	14 JAN 2021
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Collection time (00:00 - 23:59)	12:20
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Collection Date and Time (derived)	14 JAN 2021 12:20
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US3752366

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3752366

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 FEB 2021
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 12:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	09 FEB 2021
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 13:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752366

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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

US3752366

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 09 FEB 2021

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 09 FEB 2021 12:30

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

US3752366

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:39:18

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752366

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:39:18

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752366

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 APR 2021
Time of assessment (<i>00:00-23:59</i>)	12:50 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 12:50
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752366

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 APR 2021

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

US3752366

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 13:42:12

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 APR 2021

Collection time (00:00-23:59)

12:55 (24 HR)

Collection date and time (derived)

07 APR 2021 12:55

US3752366

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 19:43:30

Generated On: 12 Aug 2021 13:21:23

AEID	USA-US113-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	4 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)	16 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 19:43:30

Generated On: 12 Aug 2021 13:21:23

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	SUBJECT EXPOSED TO COVID POSITIVE PERSON THE MONDAY PRIOR TO FIRST DOSE. INVESTIGATIONAL PRODUCT WITHDRAWN
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 19:43:30

Generated On: 12 Aug 2021 13:21:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

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

Yes ☒

No ☐

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

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

2 TO 3 TIMES PER WEEK

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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"/>

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1000

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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US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 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) 06 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"/>

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SEASONAL
INFLUENZA

Dose per administration 0.5

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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US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 19:43:31

Generated On: 12 Aug 2021 13:21:23

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
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"/>

US3752366

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Mar 2021 00:39:18

Generated On: 12 Aug 2021 13:21:23

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3752366

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 19:43:32

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy) 8 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 checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 03 Apr 2021 11:24:28

Generated On: 12 Aug 2021 13:21:23

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/SEP/2020 12:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/SEP/2020 09:57
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

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:12
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

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:25
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

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 19:43:33

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US113-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:35
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

US3752366 (Prod: Baptist Health Center for Clinical Research)

US3752366

Form: Participant Creation

Generated On: 12 Aug 2021 13:21:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered 'US3752366'	RWS_ENDPOINT	02 Sep 2020 18:14:51
	ENDPOINT (b) (4)	

US3752366

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:23

US3752366

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:52

US3752366

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:23

US3752366

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'SCRN'	System	03 Sep 2020 21:00:23

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:54

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '49'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'YEARS'	System	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '49'	System	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:41

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'Sep 2020'	System	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '2020'	System	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:17

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:14:52

US3752366

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'I'	System	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:21:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:00:58

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Conjunctival infections, irritations and inflammations, PT: Conjunctivitis allergic, LLT: Allergic conjunctivitis - version MedDRA\\23.0.	(b) (4)	03 Sep 2020 21:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 21:03:45
Data point term sent to Coder	(b) (4)	03 Sep 2020 21:02:15
User entered 'Allergic conjunctivitis'	System	03 Sep 2020 21:01:16
	(b) (4), (b) (6)	

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:29:33
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:43:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:42:57
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 15:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:57
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'Jan 1990'	System	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '1990'	System	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:01:16

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 21:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 21:03:45
Data point term sent to Coder	System	03 Sep 2020 21:02:15
User entered 'Allergic rhinitis'	(b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'Jan 1990'	System	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '1990'	System	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:01:43

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Subacromial decompression - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 07:02:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:02:39
Data point term sent to Coder	System	03 Sep 2020 21:03:21
User entered 'Decompression left subacromial arthroscopy'	(b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:06

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 21:05:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:05:40
Data point term sent to Coder	System	03 Sep 2020 21:04:24
User entered 'LASIK eye surgery'	(b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	03 Sep 2020 21:03:23

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Dec 2020 05:08:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 05:08:01
User closed query 'Per MM, please review and update the term to reflect the final diagnosis' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:10:12
Query 'Per MM, please review and update the term to reflect the final diagnosis' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:48:55
Data point term sent to Coder	System	02 Dec 2020 14:48:48
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 14:48:47
User entered 'GRADE I CARDIAC MURMUR (final diagnosis unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 14:48:47
User opened query 'Per MM, please review and update the term to reflect the final diagnosis' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 20:49:25
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:37:22
Data point term sent to Coder	System	05 Nov 2020 16:36:20
User entered 'Grade I cardiac murmur'	(b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered empty.	System	05 Nov 2020 16:36:04

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:28'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '02 Sep 2020 13:28'	System	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '71' in	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '251' lb	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered '35.08059'	System	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'kg/m2'	System	03 Sep 2020 21:04:02
DataPoint set to visible.	System	02 Sep 2020 19:30:22

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'bpm'	System	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'breaths/min'	System	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'mmHg'	System	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User entered 'mmHg'	System	03 Sep 2020 21:04:02

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40

US3752366

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40

US3752366

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:10:33
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:09:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:06:53
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:04:12

US3752366

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:10:33
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:09:36
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:09:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 16:06:53
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:06:53
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 13:43:57
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:43:57
Comment added 'Physical exam date and screening date are the same. query?'.	(b) (4), (b) (6)	10 Sep 2020 13:38:30
Comment added 'Physical exam date is the same as screening visit date. Query?'.	(b) (4), (b) (6)	09 Sep 2020 20:05:48
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 16:15:28
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 21:04:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:09:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:12

US3752366

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:27

US3752366

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:27

US3752366

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:27

US3752366

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'VISIT1'	System	03 Sep 2020 21:05:27

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:04:53

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '111046'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:04:53

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	
	RWS_ENDPOINT	02 Sep 2020 19:04:53
	ENDPOINT (b) (4)	

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:28:52
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 21:05:44
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:05:39
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 19:21:29

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:39

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:39

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:39

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:05:39

US3752366

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:42:46
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:05:15
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:05:07
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:48:53
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:57:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:15

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:28'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '02 Sep 2020 13:28'	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:06:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'bpm'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'breaths/min'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '112' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'mmHg'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:06:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:06:47
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:06:47
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'mmHg'	System	03 Sep 2020 21:06:47
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '14:55' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '02 Sep 2020 14:55'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '98.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:07:36
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'bpm'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'breaths/min'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'mmHg'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 21:07:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 21:07:36
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:07:36
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 21:06:22
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'mmHg'	System	03 Sep 2020 21:07:36
User entered empty.	System	03 Sep 2020 21:06:22

US3752366

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:39:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:11:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:07:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:44:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:07:43

US3752366

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:39:52
User entered '02 Sep 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 18:11:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:07:24
User entered '02 Sep 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	10 Sep 2020 13:44:25
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:07:43

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '14:18'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '02 Sep 2020 14:18'	System	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'ONCE'	System	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:31:46

US3752366

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:07

US3752366

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:07

US3752366

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:40'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:07

US3752366

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '02 Sep 2020 13:40'	System	03 Sep 2020 21:08:07

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:38'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '02 Sep 2020 13:38'	System	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered empty.	System	03 Sep 2020 21:08:23

US3752366

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 21:08:28

US3752366

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered '1'	System	03 Sep 2020 21:08:28

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered 'Yes (Y)'	System	02 Sep 2020 19:45:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:26', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f' User entered '98.3'	System	02 Sep 2020 19:45:39
	System	02 Sep 2020 19:45:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered 'No (N)'	System	02 Sep 2020 19:45:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b42d265f-c666-479e-9957-f3c1ba5c207f'	System	02 Sep 2020 19:45:39
User entered '02 Sep 2020 14:45'	System	02 Sep 2020 19:45:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered 'Yes (Y)'	System	03 Sep 2020 02:40:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered '97.9'	System	03 Sep 2020 02:40:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:19', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered 'No (N)'	System	03 Sep 2020 02:40:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:22', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '9667ddf2-689d-4933-a27c-1b83877a1105'	System	03 Sep 2020 02:40:27
User entered '02 Sep 2020 21:40'	System	03 Sep 2020 02:40:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered 'Yes (Y)'	System	04 Sep 2020 01:59:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:17', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcf-4819-9519-2c860531bfbf' User entered '97.5'	System	04 Sep 2020 01:59:27
	System	04 Sep 2020 01:59:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcfe4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered 'No (N)'	System	04 Sep 2020 01:59:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '13e7ded5-abcfe4819-9519-2c860531bfbf'	System	04 Sep 2020 01:59:27
User entered '03 Sep 2020 20:59'	System	04 Sep 2020 01:59:27

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered 'Yes (Y)'	System	05 Sep 2020 01:36:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:28', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e' User entered '98.3'	System	05 Sep 2020 01:36:39
	System	05 Sep 2020 01:36:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:32', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered 'No (N)'	System	05 Sep 2020 01:36:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '120655b4-08e5-4c60-ae31-737c35dc6b4e'	System	05 Sep 2020 01:36:39
User entered '04 Sep 2020 20:36'	System	05 Sep 2020 01:36:39

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered 'Yes (Y)'	System	05 Sep 2020 17:02:44

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered '99.6'	System	05 Sep 2020 17:02:44

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:15', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered 'No (N)'	System	05 Sep 2020 17:02:44

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'db2b169b-456d-4d4e-a25c-225bd90b88ca'	System	05 Sep 2020 17:02:44
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:44

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:34', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '101.6'	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'TYLENOL ADDED TO CONCOMITANT MEDICATIONS' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:04:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	Amanda Horn (b) (4)	11 Sep 2020 22:03:16
User entered '1'	System	07 Sep 2020 00:44:56
	System	07 Sep 2020 00:44:56
	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '0'	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1b46e0a5-a15a-44cc-8d74-35fe944d5dd2'	System	07 Sep 2020 00:44:56
User entered '06 Sep 2020 19:44'	System	07 Sep 2020 00:44:56

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:14:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered 'Yes (Y)'	System	08 Sep 2020 03:15:12

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered '98.0'	System	08 Sep 2020 03:15:12

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:04', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered 'No (N)'	System	08 Sep 2020 03:15:12

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '6348b54b-4fb6-4b17-b9ad-d4470a985b50'	System	08 Sep 2020 03:15:12
User entered '07 Sep 2020 22:15'	System	08 Sep 2020 03:15:12

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered 'Yes (Y)'	System	09 Sep 2020 01:57:05

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered '98.6'	System	09 Sep 2020 01:57:05

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:56:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered 'No (N)'	System	09 Sep 2020 01:57:05

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:01', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '40a304f0-cfa4-4638-a20f-117dc2de3ca6'	System	09 Sep 2020 01:57:05
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 01:57:05

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'None (1)'	System	02 Sep 2020 19:46:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'No (N)'	System	02 Sep 2020 19:46:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:54', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'No (N)'	System	02 Sep 2020 19:46:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:45:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered 'None (1)'	System	02 Sep 2020 19:46:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '335bd944-4179-42f6-b670-6b0824375c48'	System	02 Sep 2020 19:46:08
User entered '02 Sep 2020 14:46'	System	02 Sep 2020 19:46:08

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'None (1)'	System	03 Sep 2020 02:40:50

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'No (N)'	System	03 Sep 2020 02:40:50

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:33', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'No (N)'	System	03 Sep 2020 02:40:50

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered 'None (1)'	System	03 Sep 2020 02:40:50

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:47', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e46f59ff-cff2-494b-90b1-f0b380179cbb'	System	03 Sep 2020 02:40:50
User entered '02 Sep 2020 21:40'	System	03 Sep 2020 02:40:50

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'None (1)'	System	04 Sep 2020 01:59:48

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:38', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'No (N)'	System	04 Sep 2020 01:59:48

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'No (N)'	System	04 Sep 2020 01:59:48

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered 'None (1)'	System	04 Sep 2020 01:59:48

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '39a7e73f-3e1e-4a9f-8536-99e66ab1ef4f'	System	04 Sep 2020 01:59:48
User entered '03 Sep 2020 20:59'	System	04 Sep 2020 01:59:48

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'None (1)'	System	05 Sep 2020 01:37:03

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'No (N)'	System	05 Sep 2020 01:37:03

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:55', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'No (N)'	System	05 Sep 2020 01:37:03

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:36:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered 'None (1)'	System	05 Sep 2020 01:37:03

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0a43deb6-1064-4280-8965-c33b22c51499'	System	05 Sep 2020 01:37:03
User entered '04 Sep 2020 20:37'	System	05 Sep 2020 01:37:03

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:39', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'None (1)'	System	05 Sep 2020 17:02:54

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'No (N)'	System	05 Sep 2020 17:02:54

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'No (N)'	System	05 Sep 2020 17:02:54

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered 'None (1)'	System	05 Sep 2020 17:02:54

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:02:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'ca65d1b6-cfe7-4b87-b8fa-4c7804b20c19'	System	05 Sep 2020 17:02:54
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:54

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'None (1)'	System	07 Sep 2020 00:45:11

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:44:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'No (N)'	System	07 Sep 2020 00:45:11

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'No (N)'	System	07 Sep 2020 00:45:11

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered 'None (1)'	System	07 Sep 2020 00:45:11

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4acca04a-866c-48a8-ae5b-9c53204145e1'	System	07 Sep 2020 00:45:11
User entered '06 Sep 2020 19:45'	System	07 Sep 2020 00:45:11

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'None (1)'	System	08 Sep 2020 03:15:40

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:14', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'No (N)'	System	08 Sep 2020 03:15:40

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:32', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'No (N)'	System	08 Sep 2020 03:15:40

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:33', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered 'None (1)'	System	08 Sep 2020 03:15:40

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:37', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '15598095-1267-4d45-a853-5e7909abd0e2'	System	08 Sep 2020 03:15:40
User entered '07 Sep 2020 22:15'	System	08 Sep 2020 03:15:40

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'None (1)'	System	09 Sep 2020 01:57:20

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:09', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'No (N)'	System	09 Sep 2020 01:57:20

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:11', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'No (N)'	System	09 Sep 2020 01:57:20

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:12', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered 'None (1)'	System	09 Sep 2020 01:57:20

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'a2abdf80-7ef8-4229-ad36-5b11db47396d'	System	09 Sep 2020 01:57:20
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 01:57:20

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:17', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:21', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:26', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'None (0)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered 'No (N)'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T14:46:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '603fd5e9-cff0-41b2-a686-3abdb4e4491c'	System	02 Sep 2020 19:46:42
User entered '02 Sep 2020 14:46'	System	02 Sep 2020 19:46:42

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 14:38'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 17:08'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:55', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:57', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:40:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'None (0)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered 'No (N)'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-02T21:41:08', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fda6cdc9-ae8f-4c3d-a405-378d368af507'	System	03 Sep 2020 02:41:11
User entered '02 Sep 2020 21:41'	System	03 Sep 2020 02:41:11

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '02 Sep 2020 18:03'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 2'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:49', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:53', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:54', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'None (0)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T20:59:59', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered 'No (N)'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-03T21:00:03', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd2fe776f-1835-4b81-a7eb-8fe1327841b2'	System	04 Sep 2020 02:00:20
User entered '03 Sep 2020 21:00'	System	04 Sep 2020 02:00:20

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 3'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:10', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:14', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:16', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:21', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:23', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'None (0)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:27', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered 'No (N)'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-04T20:37:31', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2969b99b-ec61-4887-9d3d-188e6e642186'	System	05 Sep 2020 01:37:37
User entered '04 Sep 2020 20:37'	System	05 Sep 2020 01:37:37

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 4'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:27', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Some interference with activity (2)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:41', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'None (0)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:49', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:03:52', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'None (0)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:04:13', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Prevents daily activity and requires medical attention (3)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:04:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered 'Yes (Y)'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-05T12:05:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '5bfe111e-7ca3-49bc-ad78-b8fb91c3f6da'	System	05 Sep 2020 17:05:34
User entered '05 Sep 2020 12:05'	System	05 Sep 2020 17:05:34

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 5'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:29', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:43', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'None (0)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:45:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:46:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered 'No (N)'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-06T19:46:03', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'b9947a8b-06b8-41bb-ad95-01765e74bcc8'	System	07 Sep 2020 00:46:04
User entered '06 Sep 2020 19:46'	System	07 Sep 2020 00:46:04

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 6'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:50', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:15:58', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:02', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:04', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'None (0)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'None (0)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:09', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered 'No (N)'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-07T22:16:12', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7ab79bb5-a81d-4f1c-ab3d-52fb976c7219'	System	08 Sep 2020 03:16:16
User entered '07 Sep 2020 22:16'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 7'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:57:56', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:05', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:15', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:20', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'None (0)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:35', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered 'No (N)'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-08T20:58:39', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ca3fe40-6c92-47de-bf84-ca053d5a89d8'	System	09 Sep 2020 02:22:45
User entered '08 Sep 2020 20:58'	System	09 Sep 2020 02:22:45

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	08 Sep 2020 03:16:16
User entered 'Day 8'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:42', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd36ff91d-de8b-489d-8be6-7acb0d525c5f'	System	09 Sep 2020 21:37:51
User entered 'None (0)'	System	09 Sep 2020 21:37:51

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:45', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd36ff91d-de8b-489d-8be6-7acb0d525c5f'	System	09 Sep 2020 21:37:51
User entered '09 Sep 2020 16:37'	System	09 Sep 2020 21:37:51

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	08 Sep 2020 03:16:16
User entered 'Day 8'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0c7f1066-fa15-4ba6-83e9-51ab2022a87f'	System	09 Sep 2020 21:37:57
User entered 'No (N)'	System	09 Sep 2020 21:37:57

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-09-09T16:37:53', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0c7f1066-fa15-4ba6-83e9-51ab2022a87f' User entered '09 Sep 2020 16:37'	System	09 Sep 2020 21:37:57
	System	09 Sep 2020 21:37:57

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 03:16:16

US3752366

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 03:16:16

US3752366

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:28:44

US3752366

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:28:44

US3752366

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:28:44

US3752366

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:28:44

US3752366

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:30:46

US3752366

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'I'	System	25 Sep 2020 19:30:46

US3752366

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:31:07

US3752366

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:31:07

US3752366

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:31:07

US3752366

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:31:07

US3752366

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:31:42

US3752366

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:17:48
User entered 'I'	System	25 Sep 2020 19:31:42

US3752366

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:32:00

US3752366

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:32:00

US3752366

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:32:00

US3752366

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:32:00

US3752366

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:38:55

US3752366

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User entered '1'	System	07 Oct 2020 19:38:55

US3752366

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:48:54

US3752366

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:48:54

US3752366

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:48:54

US3752366

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'VISIT2'	System	07 Oct 2020 19:48:54

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:20'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '07 Oct 2020 13:20'	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '76'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'bpm'	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'breaths/min'	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '114'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'mmHg'	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '76'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'mmHg'	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:00

US3752366

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:11

US3752366

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		31 Mar 2021 19:25:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:11

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 19:51:05
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:51:05
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	07 Oct 2020 19:50:20
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:50:20

US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 07OCT2020. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 08:21:56
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 07OCT2020. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'Sample collected and shipped. Accession number: 1F623266897' (Site from DM).	Lauren Evans (b) (4)	10 Mar 2021 21:33:15
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 07OCT2020. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:17:00
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:53:56
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' answered with 'Date is correct. Sample collected visit 2 day 29' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:22:38
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 07OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:30:44

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EAB) (1725)

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US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:51:28

US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:28

US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
User entered '13:47'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:28

US3752366

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '07 Oct 2020 13:47'	System	07 Oct 2020 19:51:28

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'Collection 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	31 Mar 2021 19:25:35
User opened query 'Collection 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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User closed query 'Per GCL Lab Reconciliation re-query: Swab: response noted. Please confirm if an unscheduled lab kit was used for visit 2 day 2.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 11:56:13
Query 'Per GCL Lab Reconciliation re-query: Swab: response noted. Please confirm if an unscheduled lab kit was used for visit 2 day 2.' answered with 'it was visit 2; unscheduled kits were all that were available' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:38:12
User opened query 'Per GCL Lab Reconciliation re-query: Swab: response noted. Please confirm if an unscheduled lab kit was used for visit 2 day 2.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:13:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 14:13:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Sample was collected on 07OCT2020' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 18:15:50

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under “Unscheduled” visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM). User entered '07 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 04:38:27
	(b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '13:52'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '07 Oct 2020 13:52'	System	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered empty.	System	07 Oct 2020 19:51:46

US3752366

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:51:51

US3752366

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'I'	System	07 Oct 2020 19:51:51

US3752366

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4)	14 Oct 2020 21:33:23
	Amanda Horn (b) (4)	
	(b) (4)	

US3752366

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Oct 2020'	(b) (4)	
	Amanda Horn (b) (4)	14 Oct 2020 21:33:23
	(b) (4)	

US3752366

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	14 Oct 2020 21:33:23

US3752366

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	14 Oct 2020 21:33:23
	(b) (4)	

US3752366

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4)	14 Oct 2020 21:33:29
	Amanda Horn (b) (4)	
	(b) (4)	

US3752366

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User entered 'I'	System	14 Oct 2020 21:33:29

US3752366

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4)	23 Oct 2020 12:50:19
	Amanda Horn (b) (4)	
	(b) (4)	

US3752366

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '22 Oct 2020'	(b) (4)	
	Amanda Horn (b) (4)	23 Oct 2020 12:50:19
	(b) (4)	

US3752366

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	23 Oct 2020 12:50:19

US3752366

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	23 Oct 2020 12:50:19
	(b) (4)	

US3752366

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:27

US3752366

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User entered 'I'	System	05 Nov 2020 16:36:27

US3752366

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:12
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 18:04:12
	(b) (4)	

US3752366

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:12
User entered '28 Oct 2020'	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 18:04:12
	(b) (4)	

US3752366

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 18:04:12
	(b) (4)	

US3752366

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:12
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 18:04:12
	(b) (4)	

US3752366

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:36

US3752366

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:08
User entered 'I'	System	05 Nov 2020 16:36:36

US3752366

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:50

US3752366

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:50

US3752366

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:36:50

US3752366

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'VISIT3'	System	05 Nov 2020 16:36:50

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '12:40'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '04 Nov 2020 12:40'	System	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '73'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'bpm'	System	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'breaths/min'	System	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '124'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'mmHg'	System	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '86'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'mmHg'	System	05 Nov 2020 16:37:25

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37

US3752366

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37

US3752366

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:33

US3752366

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		31 Mar 2021 19:25:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).		31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:33

US3752366

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:52

US3752366

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:52

US3752366

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered '12:52'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:52

US3752366

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '04 Nov 2020 12:52'	System	05 Nov 2020 16:37:52

US3752366

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:04

US3752366

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered 'I'	System	05 Nov 2020 16:38:04

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 64'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-06T00:13:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered 'No (N)'	System	06 Nov 2020 06:13:29

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-06T00:13:19', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered 'No (N)'	System	06 Nov 2020 06:13:29

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-06T00:13:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'bd2f8369-3fc3-4dc2-bfa4-362332844b88'	System	06 Nov 2020 06:13:29
User entered '06 Nov 2020 00:13:25'	System	06 Nov 2020 06:13:29

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 71'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-11T06:43:10', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered 'No (N)'	System	11 Nov 2020 12:43:33

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-11T06:43:25', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered 'No (N)'	System	11 Nov 2020 12:43:33

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-11T06:43:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'e61f19ac-20da-49ff-9f00-ec987177c6aa'	System	11 Nov 2020 12:43:33
User entered '11 Nov 2020 06:43:30'	System	11 Nov 2020 12:43:33

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered 'Day 78'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-19T07:50:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered 'No (N)'	System	19 Nov 2020 13:50:51

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-19T07:50:41', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered 'No (N)'	System	19 Nov 2020 13:50:51

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-19T07:50:46', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '1ce76820-6bd6-4743-9984-51855a273bb6'	System	19 Nov 2020 13:50:51
User entered '19 Nov 2020 07:50:46'	System	19 Nov 2020 13:50:51

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 19:31:46

US3752366

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:02:51
Data entry locked.	System	02 Sep 2020 19:31:46
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 19:31:46

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-27T09:33:15', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2b367bdc-d0ec-4288-809b-0f1640649487'	System	27 Nov 2020 15:33:29
User entered 'No (N)'	System	27 Nov 2020 15:33:29

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-27T09:33:18', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2b367bdc-d0ec-4288-809b-0f1640649487'	System	27 Nov 2020 15:33:29
User entered 'No (N)'	System	27 Nov 2020 15:33:29

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-11-27T09:33:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2b367bdc-d0ec-4288-809b-0f1640649487'	System	27 Nov 2020 15:33:29
User entered '27 Nov 2020 09:33:24'	System	27 Nov 2020 15:33:29

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-08T12:16:53', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0595bbe-6fc8-4027-aa6e-30631b91192d'	System	08 Dec 2020 18:20:11
User entered 'No (N)'	System	08 Dec 2020 18:20:11

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-08T12:17:12', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0595bbe-6fc8-4027-aa6e-30631b91192d'	System	08 Dec 2020 18:20:11
User entered 'No (N)'	System	08 Dec 2020 18:20:11

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-08T12:20:06', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0595bbe-6fc8-4027-aa6e-30631b91192d'	System	08 Dec 2020 18:20:11
User entered '08 Dec 2020 12:20:06'	System	08 Dec 2020 18:20:11

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-22T11:51:01', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2dfa59c8-8000-45d9-9471-590a2788c07d'	System	22 Dec 2020 17:51:39
User entered 'No (N)'	System	22 Dec 2020 17:51:39

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-22T11:51:27', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2dfa59c8-8000-45d9-9471-590a2788c07d'	System	22 Dec 2020 17:51:39
User entered 'No (N)'	System	22 Dec 2020 17:51:39

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2020-12-22T11:51:32', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '2dfa59c8-8000-45d9-9471-590a2788c07d' User entered '22 Dec 2020 11:51:32'	System	22 Dec 2020 17:51:39
	System	22 Dec 2020 17:51:39

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-12T11:48:24', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0b1d9dc0-83ab-4237-a53d-ee0732eae794'	System	12 Jan 2021 17:48:36
User entered 'No (N)'	System	12 Jan 2021 17:48:36

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-12T11:48:30', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0b1d9dc0-83ab-4237-a53d-ee0732eae794'	System	12 Jan 2021 17:48:36
User entered 'No (N)'	System	12 Jan 2021 17:48:36

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-12T11:48:34', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '0b1d9dc0-83ab-4237-a53d-ee0732eae794'	System	12 Jan 2021 17:48:36
User entered '12 Jan 2021 11:48:34'	System	12 Jan 2021 17:48:36

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-15T06:51:36', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fdf194c0-2433-497e-9d89-fa5edef9fc7c'	System	15 Jan 2021 12:51:47
User entered 'No (N)'	System	15 Jan 2021 12:51:47

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-15T06:51:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fdf194c0-2433-497e-9d89-fa5edef9fc7c'	System	15 Jan 2021 12:51:47
User entered 'No (N)'	System	15 Jan 2021 12:51:47

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-15T06:51:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'fdf194c0-2433-497e-9d89-fa5edef9fc7c'	System	15 Jan 2021 12:51:47
User entered '15 Jan 2021 06:51:44'	System	15 Jan 2021 12:51:47

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-22T00:10:37', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4596b568-5033-4532-8c8a-3aeab145e3b7'	System	22 Jan 2021 06:10:57
User entered 'No (N)'	System	22 Jan 2021 06:10:57

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-22T00:10:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4596b568-5033-4532-8c8a-3aeab145e3b7'	System	22 Jan 2021 06:10:57
User entered 'No (N)'	System	22 Jan 2021 06:10:57

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-22T00:10:55', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '4596b568-5033-4532-8c8a-3aeab145e3b7'	System	22 Jan 2021 06:10:57
User entered '22 Jan 2021 00:10:55'	System	22 Jan 2021 06:10:57

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-30T11:14:03', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '8c60434f-6a64-40ef-8bc9-201db26e1535'	System	30 Jan 2021 17:14:13
User entered 'No (N)'	System	30 Jan 2021 17:14:13

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-30T11:14:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '8c60434f-6a64-40ef-8bc9-201db26e1535'	System	30 Jan 2021 17:14:13
User entered 'No (N)'	System	30 Jan 2021 17:14:13

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-01-30T11:14:10', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '8c60434f-6a64-40ef-8bc9-201db26e1535'	System	30 Jan 2021 17:14:13
User entered '30 Jan 2021 11:14:10'	System	30 Jan 2021 17:14:13

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-09T12:17:01', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'eb403ac2-ab79-4827-aaf1-50968e137590'	System	09 Feb 2021 18:17:28
User entered 'No (N)'	System	09 Feb 2021 18:17:28

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-09T12:17:04', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'eb403ac2-ab79-4827-aaf1-50968e137590'	System	09 Feb 2021 18:17:28
User entered 'No (N)'	System	09 Feb 2021 18:17:28

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-09T12:17:07', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'eb403ac2-ab79-4827-aaf1-50968e137590'	System	09 Feb 2021 18:17:28
User entered '09 Feb 2021 12:17:07'	System	09 Feb 2021 18:17:28

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-12T07:00:40', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'de6abea4-1e86-4259-8ab2-8422c4c7fdf6'	System	12 Feb 2021 13:00:52
User entered 'No (N)'	System	12 Feb 2021 13:00:52

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-12T07:00:44', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'de6abea4-1e86-4259-8ab2-8422c4c7fdf6'	System	12 Feb 2021 13:00:52
User entered 'No (N)'	System	12 Feb 2021 13:00:52

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-12T07:00:48', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'de6abea4-1e86-4259-8ab2-8422c4c7fdf6'	System	12 Feb 2021 13:00:52
User entered '12 Feb 2021 07:00:48'	System	12 Feb 2021 13:00:52

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-19T12:08:51', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'cc6f9f6a-fe60-4994-88c1-50a31fcefdeb'	System	19 Feb 2021 18:11:55
User entered 'No (N)'	System	19 Feb 2021 18:11:55

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-19T12:08:54', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'cc6f9f6a-fe60-4994-88c1-50a31fcefdeb'	System	19 Feb 2021 18:11:55
User entered 'No (N)'	System	19 Feb 2021 18:11:55

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-19T12:08:57', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'cc6f9f6a-fe60-4994-88c1-50a31fcefdeb'	System	19 Feb 2021 18:11:55
User entered '19 Feb 2021 12:08:57'	System	19 Feb 2021 18:11:55

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-26T06:49:21-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '487d1f44-336f-4f82-a18d-d068edd917fe' User entered 'No (N)'	System	26 Feb 2021 12:49:35
	System	26 Feb 2021 12:49:35

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-26T06:49:26-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '487d1f44-336f-4f82-a18d-d068edd917fe' User entered 'No (N)'	System	26 Feb 2021 12:49:35

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-02-26T06:49:29-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '487d1f44-336f-4f82-a18d-d068edd917fe' User entered '26 Feb 2021 06:49:29'	System	26 Feb 2021 12:49:35
	System	26 Feb 2021 12:49:35

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-05T06:51:15-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd5d6de88-a538-4650-af87-3e8e7f0cfdd6'	System	05 Mar 2021 12:51:26
User entered 'No (N)'	System	05 Mar 2021 12:51:26

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-05T06:51:18-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd5d6de88-a538-4650-af87-3e8e7f0cfdd6'	System	05 Mar 2021 12:51:26
User entered 'No (N)'	System	05 Mar 2021 12:51:26

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-05T06:51:21-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'd5d6de88-a538-4650-af87-3e8e7f0cfdd6'	System	05 Mar 2021 12:51:26
User entered '05 Mar 2021 06:51:21'	System	05 Mar 2021 12:51:26

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-21T23:34:08-04:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0826a6e-ce05-470e-bb10-da40a62cd58c'	System	22 Mar 2021 03:34:20
User entered 'No (N)'	System	22 Mar 2021 03:34:20

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-21T23:34:11-04:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0826a6e-ce05-470e-bb10-da40a62cd58c'	System	22 Mar 2021 03:34:20
User entered 'No (N)'	System	22 Mar 2021 03:34:20

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-21T23:34:14-04:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: 'c0826a6e-ce05-470e-bb10-da40a62cd58c' User entered '21 Mar 2021 23:34:14'	System	22 Mar 2021 03:34:20
	System	22 Mar 2021 03:34:20

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-30T18:31:38-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '16459f99-9665-4084-8a4d-6aa0a395a4d4'	System	30 Mar 2021 23:31:49
User entered 'No (N)'	System	30 Mar 2021 23:31:49

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-30T18:31:40-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '16459f99-9665-4084-8a4d-6aa0a395a4d4'	System	30 Mar 2021 23:31:49
User entered 'No (N)'	System	30 Mar 2021 23:31:49

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-30T18:31:43-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '16459f99-9665-4084-8a4d-6aa0a395a4d4'	System	30 Mar 2021 23:31:49
User entered '30 Mar 2021 18:31:43'	System	30 Mar 2021 23:31:49

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Date and time of submission](#)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-04-24T15:30:46-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7e0b9b2c-29f8-4bf8-8fd0-1caf39db38e2'	System	24 Apr 2021 20:30:56
User entered 'No (N)'	System	24 Apr 2021 20:30:56
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-04-24T15:30:48-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7e0b9b2c-29f8-4bf8-8fd0-1caf39db38e2'	System	24 Apr 2021 20:30:56
User entered 'No (N)'	System	24 Apr 2021 20:30:56
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-04-24T15:30:52-05:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '7e0b9b2c-29f8-4bf8-8fd0-1caf39db38e2'	System	24 Apr 2021 20:30:56
User entered '24 Apr 2021 15:30:52'	System	24 Apr 2021 20:30:56
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

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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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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)
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US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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US3752366

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[Date and time of submission](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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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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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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)
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US3752366

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US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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?

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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US3752366

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	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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Form: Safety Follow Up Diary

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[New loss of smell](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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US3752366

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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?](#)

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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US3752366

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	31 Mar 2021 19:25:35
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US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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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)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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[Date and time of submission](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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US3752366

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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?

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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US3752366

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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)
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US3752366

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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[New loss of smell](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

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[Congestion](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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US3752366

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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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US3752366

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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	31 Mar 2021 19:25:35
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US3752366

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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US3752366

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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US3752366

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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?](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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[Congestion](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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[Nausea](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

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US3752366

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[Diarrhea](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:49:03

US3752366

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?](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

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[Chills](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

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US3752366

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[Difficulty breathing](#)

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US3752366

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[Fatigue](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

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[Body aches](#)

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[Headache](#)

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[New loss of taste](#)

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[New loss of smell](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

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?](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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[Congestion](#)

Audit	User	Time (GMT)
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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US3752366

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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Fever (Temperature \geq 100.4°F/38°C)

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Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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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DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

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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DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
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US3752366

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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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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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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US3752366

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

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US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

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	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:49:03

US3752366

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	31 Mar 2021 19:25:35
DataPoint Inactivated.	System	31 Mar 2021 19:23:51
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:03
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:49:03

US3752366

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:21:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:06:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-03T06:54:08-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '19411ff4-088e-4e19-8be0-da005e8f0b2e'	System	03 Mar 2021 12:54:17
User entered 'No (N)'	System	03 Mar 2021 12:54:17

US3752366

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:21:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:06:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a7df3d2377246f6)', Time: '2021-03-03T06:54:14-06:00', User OID: 'PatientReportedOutcome (US3752366)', ODM File OID: '19411ff4-088e-4e19-8be0-da005e8f0b2e' User entered '03 Mar 2021 06:54:14'	System	03 Mar 2021 12:54:17
	System	03 Mar 2021 12:54:17

US3752366

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:18:04

US3752366

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:18:04

US3752366

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:18:04

US3752366

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:18:04

US3752366

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:18:08

US3752366

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:55:37
User entered '1'	System	02 Dec 2020 14:18:08

US3752366

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:44:35

US3752366

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 15:44:35

US3752366

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 15:44:35

US3752366

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 15:44:35

US3752366

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:48:14

US3752366

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User entered 'I'	System	06 Jan 2021 15:48:14

US3752366

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	09 Mar 2021 16:06:59
	(b) (4)	

US3752366

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered '4 Feb 2021'	Amanda Horn (b) (4)	09 Mar 2021 16:06:59
	(b) (4)	

US3752366

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	09 Mar 2021 16:06:59
	(b) (4)	

US3752366

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 16:06:59
	(b) (4)	

US3752366

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	09 Mar 2021 16:07:04
	(b) (4)	

US3752366

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User entered 'I'	System	09 Mar 2021 16:07:04

US3752366

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered 'Yes (Y)'	Amanda Horn (b) (4)	09 Mar 2021 16:07:35
	(b) (4)	

US3752366

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered '8 Mar 2021'	Amanda Horn (b) (4)	09 Mar 2021 16:07:35
	(b) (4)	

US3752366

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	09 Mar 2021 16:07:35
	(b) (4)	

US3752366

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	09 Mar 2021 16:07:35
	(b) (4)	

US3752366

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
	(b) (4)	
Signature has been broken.	Haylee Rowe (b) (4)	07 Apr 2021 18:21:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	07 Apr 2021 18:21:07
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:31:22
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	16 Mar 2021 19:15:10
User entered 'Yes (Y)'	Lauren Evans (b) (4)	16 Mar 2021 19:14:40

US3752366

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:33
User entered '1'	System	07 Apr 2021 18:21:07
User entered empty.	System	16 Mar 2021 19:15:10
User entered '1'	System	16 Mar 2021 19:14:40

US3752366

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:33:40

US3752366

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:33:40

US3752366

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:33:40

US3752366

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered 'VISIT4'	System	07 Apr 2021 18:33:40

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '12:50'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered '07 Apr 2021 12:50'	System	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '70'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered 'bpm'	System	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered 'breaths/min'	System	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '122'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered 'mmHg'	System	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '78'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered 'mmHg'	System	07 Apr 2021 18:34:09

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51

US3752366

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51

US3752366

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:21

US3752366

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:21

US3752366

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33

US3752366

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33

US3752366

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '12:55'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:33

US3752366

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered '07 Apr 2021 12:55'	System	07 Apr 2021 18:34:33

US3752366

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:39

US3752366

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:32:51
User entered '1'	System	07 Apr 2021 18:34:39

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:06:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered '6 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:06:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 02:37:41
User closed query 'Per source time of contact is noted as "1745"please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:37:39
Query 'Per source time of contact is noted as "1745"please verify and update EDC. ' answered by data change (Site from CRA).	System	11 Nov 2020 20:24:39
User entered '17:45' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 20:24:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:10:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User opened query 'Per source time of contact is noted as "1745"please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:09:40
User entered '13:27'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:06:49
User entered '6 Sep 2020 17:45'	System	11 Nov 2020 20:24:39
User entered '6 Sep 2020 13:27'	System	07 Sep 2020 00:59:55

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:06:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:06:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:09:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 00:59:55

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:32:58
User closed query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:37:53
Query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' answered with 'RECONCILED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:18:14
Query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' answered by data change (Site from CRA).	System	10 Nov 2020 22:02:40
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
User opened query 'Subject's 1 day of symptoms started on 04Sep2020.Please verify and update EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:29:56
User opened query 'Per CDM: it appears that Day 1 is missing and Day 2 date of 09SEP2020 is after Contact Date of 06SEP2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:19:44
User entered 'Day 2 (Day 2)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:28
User entered '4 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '9 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:33
User entered '99.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:43:39
User entered '098.1' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:14
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	10 Sep 2020 22:42:54
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:05:58
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:05:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:10:23
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	10 Sep 2020 22:42:54
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:44
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:56
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:06:57
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:42:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 3 (Day 3)'	(b) (4)	
	Amanda Horn (b) (4)	10 Sep 2020 22:44:29
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:07:10
User entered '5 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:07:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:07:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:07:28
User entered '101.6' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:43:54
User entered '099.0' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:17
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:21
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:24
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 22:59:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:17:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:08:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:44:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 4 (Day 4)'	(b) (4)	
	Amanda Horn (b) (4)	11 Sep 2020 22:04:59
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:30
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '11 Sep 2020'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:31
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:33
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered empty.	System	11 Nov 2020 23:00:48
User entered '%'	System	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:34
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:36
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:37
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:40
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:41
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:42
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:44
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:47
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:48
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:49
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:51
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Severe (Severe)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:53
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:54
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:57
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:58
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:09:59
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:01
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:04:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 5 (Day 5)'	(b) (4)	
	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:11
User entered '7 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '12 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:12
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:14
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered empty.	System	11 Nov 2020 23:01:51
User entered '%'	System	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:15
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.2' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:16
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:18
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:20
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:21
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:23
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:24
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:26
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:27
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:29
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:30
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Moderate (Moderate)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:32
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:34
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:35
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:36
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:38
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:39
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:01:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 6 (Day 6)'	(b) (4)	
	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:54
User entered '8 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '13 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Source says temp is 98.0--please correct in EDC or clarify.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:10:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 22:10:52
Query 'Source says temp is 98.0--please correct in EDC or clarify.' answered with 'updated' (Site from CRA).	Amanda Horn (b) (4) (b) (4)	01 Dec 2020 21:34:17
User entered '98.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	01 Dec 2020 21:34:09
User opened query 'Source says temp is 98.0--please correct in EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 19:26:09
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99.7' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:48:46
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:48:43
User closed query 'Please review subject illness visit 1 progress note on 08Sep2020 and clarify for all "NOT DONE" entries.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:36:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
Query 'Please review subject illness visit 1 progress note on 08Sep2020 and clarify for all "NOT DONE" entries.' answered with 'UPDATED' (Site from CRA).	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 21:34:05
	(b) (4)	
DataPoint Un-verified.	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
	(b) (4)	
User opened query 'Please review subject illness visit 1 progress note on 08Sep2020 and clarify for all "NOT DONE" entries.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:30:59
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:26:32
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:26:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:26:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4), (b) (6)	14 Sep 2020 21:50:14
	Amanda Horn (b) (4)	
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:26:57
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:27:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 23:05:28
DataPoint Un-verified.	Amanda Horn (b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	(b) (4)	14 Sep 2020 21:50:14

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Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:33:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	02 Feb 2021 21:33:56
DataPoint Verified.	(b) (4)	01 Dec 2020 19:27:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:05:28
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 7 (Day 7)'	(b) (4)	
	Amanda Horn (b) (4)	14 Sep 2020 21:50:14
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:24
User entered '9 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '14 Sep 2020'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:29
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.7' F	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:56
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:58
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:06
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:29:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	14 Sep 2020 21:50:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 8 (Day 8)'	(b) (4)	
	Amanda Horn (b) (4)	16 Sep 2020 18:01:59
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:40
User entered '10 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '15 Sep 2020'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:45
User entered '99.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.4' F	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:01
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:05
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:09
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:30:54
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:22
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 18:01:59

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 9 (Day 9)'	(b) (4)	
	Amanda Horn (b) (4)	21 Sep 2020 15:01:04
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:42
User entered '11 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '16 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '100'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:31:51
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:36
User entered '098.1' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:00
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:08
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:19
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:25
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:27
User entered 'Severe (Severe)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:46
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:32:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 10 (Day 10)'	(b) (4)	
	Amanda Horn (b) (4)	21 Sep 2020 15:01:47
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:13
User entered '12 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '17 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:15
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:18
User entered '98.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:48
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	21 Sep 2020 15:01:47
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4)	21 Sep 2020 15:01:47
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:46
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:09:26
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'Mild (Mild)'	Amanda Horn (b) (4)	21 Sep 2020 15:01:47
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:33:52
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:01:47

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:02:40
User entered 'Day 11 (Day 11)'	(b) (4)	
	Amanda Horn (b) (4)	21 Sep 2020 15:02:54
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:09
User entered '13 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:02:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '18 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:12
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:14
User entered '99.7' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:44:59
User entered '097.9' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:22
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:44
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:02:54

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 12 (Day 12)'	(b) (4)	
	Amanda Horn (b) (4)	21 Sep 2020 15:03:34
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:06
User entered '14 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '19 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:08
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:09
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	21 Sep 2020 15:03:34

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:10
User entered '98.3' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:14
User entered '097.0' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:21
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

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Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:41
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:35:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:03:34

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 13 (Day 13)'	(b) (4)	
	Amanda Horn (b) (4)	21 Sep 2020 15:04:14
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:05
User entered '15 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '20 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:08
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '98'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:11
User entered '98.4' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:28
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:19
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:21
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:22
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:24
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:38
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:04:14

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:03:36
User entered 'Day 14 (Day 14)'	(b) (4)	
	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:57
User entered '16 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
Query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit Day 28 recorded with date of 07OCT2020. Please reconcile' canceled (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:21:01
User opened query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit Day 28 recorded with date of 07OCT2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:21:05
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:00
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:13:49
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:57
User entered '100' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '99'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:01
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:13:49
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:57
User entered '98.1' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:45:49
User entered '097.2' F	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:09
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:13
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:20
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:22
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:24
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:32
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:33
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:37
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:37:40
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered 'None (None)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 22:03:36
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:01
User entered '17 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:52:06
Query 'Data is required. Please complete.' answered with 'DATA ENTRY ERROR. NO FURTHER ASSESSMENTS COMPLETED DUE TO SYMPTOM RESOLUTION' (Site from System).	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:47:23
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 16:46:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:03
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered '0'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:04
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	11 Nov 2020 23:14:31
User entered empty.	System	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:06
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:14
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:17
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:20
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:25
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:28
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:37
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:47
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4)	07 Oct 2020 16:46:29
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:38:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:14:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:26:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:24:05
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:46:29

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 15 (Day 15)'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:04
User entered '18 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:06
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:08
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	11 Nov 2020 23:15:26
User entered empty.	System	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 23:15:45
User entered '97.9' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Nov 2020 23:15:26
User entered '97.9' (non-conformant).	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:15
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:17
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:18
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:19
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:24
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:26
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:27
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:31
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:15:26
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:39:43
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:15:26
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:03:51

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 16 (Day 16)'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:40:01
User entered '19 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:40:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:40:04
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	11 Nov 2020 23:16:29
User entered empty.	System	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:40:05
User entered '97.0' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:40:07
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:51
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:56
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:49:58
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:16:29
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:01
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:03
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:16:29
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:04

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 17 (Day 17)'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:19
User entered '20 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:20
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:22
User entered '98' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	11 Nov 2020 23:17:14
User entered empty.	System	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:23
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:28
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:30
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:31
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:33
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:36
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:39
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:44
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:49
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:50
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:52
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:53
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:50:55
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:14
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:17

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Day 18 (Day 18)'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:13
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:16
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:18
User entered '99' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User entered '%'	System	11 Nov 2020 23:17:55
User entered empty.	System	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:20
User entered '97.2' F reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:22
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:23
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:25
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:28
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:29
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:31
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:32
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:34
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:35
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:38
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:40
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:41
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:42
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:45
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:17:55
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:46
User entered 'None (None)' reason for change: Data Entry Error	Amanda Horn (b) (4)	11 Nov 2020 23:17:55
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:00
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:52:29
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 14:52:34
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 06 Sep 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:06:18
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 06 Sep 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'data updated per query' (Site from DM).	Lauren Evans (b) (4)	20 Apr 2021 13:11:14
DataPoint Un-verified.	Lauren Evans (b) (4)	20 Apr 2021 13:10:55
Signature has been broken.	Lauren Evans (b) (4)	20 Apr 2021 13:10:55
User entered 'None (None)' reason for change: Data Entry Error	Lauren Evans (b) (4)	20 Apr 2021 13:10:55
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 06 Sep 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:18:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:51:48
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Nov 2020 22:04:30

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	10 Nov 2020 21:32:40
User entered '8 Sep 2020'	Amanda Horn (b) (4)	10 Sep 2020 22:45:32
	(b) (4)	

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:31:55
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'YES AND IT IS RECORDED IN ADVERSE EVENTS FORM' (Site from System).	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:50:26
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	10 Sep 2020 22:45:32
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	10 Nov 2020 21:32:40
User entered '8 Sep 2020'	Amanda Horn (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:32:40
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:05
User entered 'I'	System	10 Sep 2020 22:45:32

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

US3752366

Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:43:08
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:25:04
User closed query 'Per CDM: Re-Query: Response noted, however both Evidence of Shock and Evidence of Pneumonia are missing responses. Please review and updated accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 08:53:41
Query 'Per CDM: Re-Query: Response noted, however both Evidence of Shock and Evidence of Pneumonia are missing responses. Please review and updated accordingly. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	26 Feb 2021 20:19:36
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	26 Feb 2021 20:19:11
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	26 Feb 2021 20:19:11
User opened query 'Per CDM: Re-Query: Response noted, however both Evidence of Shock and Evidence of Pneumonia are missing responses. Please review and updated accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:50:25
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:43:35
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:45:13
User entered empty; reason for change Data Entry Error	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:45:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per CDM: Please provide a response for Evidence of Shock Requires Vasopressors and Radiographical Evidence.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:48
Query 'Per CDM: Please provide a response for Evidence of Shock Requires Vasopressors and Radiographical Evidence.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:45:23
User opened query 'Per CDM: Please provide a response for Evidence of Shock Requires Vasopressors and Radiographical Evidence.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 18:20:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	10 Nov 2020 21:42:58
	(b) (4)	
User entered '8 Sep 2020'	Amanda Horn (b) (4)	10 Sep 2020 22:47:31
	(b) (4)	

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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Generated On: 12 Aug 2021 13:21:23

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

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Generated On: 12 Aug 2021 13:21:23

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:47:31

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Folder: Covid-19 Assessment 06 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:21:23

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:07:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:21
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:47:42

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:55:22
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:39:19
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:39:19
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:55:24
User entered '10 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:39:19
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:55:44
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:55:46
User entered '12 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:56:04
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:56:10
User entered '14 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:56:25
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 17:59:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 17:59:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:53:57
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' answered with '1F636672162' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 18:04:00
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:35:31
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:35:31
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '914897858183' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	20 Jan 2021 15:04:42
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:40:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:40:00

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '914897857989' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:40:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:04:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:56:27
User entered '16 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	16 Sep 2020 17:59:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:54:25
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' answered with '1F633860258' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	21 Jan 2021 18:04:28
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however please review and provide the accession number which starts with '1F' for tracking purpose in the response.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:35:44
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:35:44
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' answered with '914897858183' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	20 Jan 2021 15:05:03
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:39:19
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:39:19

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '914897857989' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:41:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:04:40
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:56:57
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 15:21:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 15:21:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:21:50
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 28SEP2020 in PPD Central lab. Please confirm and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 07:38:26
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 28SEP2020 in PPD Central lab. Please confirm and update if applicable, thank you.' answered with 'day 21 was the 14 Sep. day 21 was the 28 Sep' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:42:13
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:57:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21SEP2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 28SEP2020 in PPD Central lab. Please confirm and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:03:41
User entered '21 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:21:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:49:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:49:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	29 Sep 2020 17:49:49
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:04:27
User entered '28 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	29 Sep 2020 17:49:49
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:59:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:48:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:53:58
Query 'Data is required. Please complete.' answered with 'Day 28 has not occurred yet' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 21:32:57
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:38:50
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:59:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:06:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'SITE DID NOT HAVE VISIT DAY 28 KIT AVAILABLE THEREFORE UNSCHEDULED KIT USED FOR SUPPLIES' (Site from DM).	Amanda Horn (b) (4) (b) (4)	02 Nov 2020 15:50:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:38:59
User entered '7 Oct 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 16:48:12
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:38:50

US3752366

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

US3752366

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

US3752366

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:55:52
User entered 'Clinic (Clinic)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:15:28

US3752366

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:06
User entered 'SICKD1'	System	08 Sep 2020 16:15:28

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:57:18
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:57:19
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:57:20
User entered '10:20'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User entered '8 Sep 2020 10:20'	System	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Please remove leading zero from all values. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:41:00
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:40:38
Query 'Please remove leading zero from all values. ' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:39:49
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User opened query 'Please remove leading zero from all values. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:57:09
User entered '098.0' F	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:51
User closed query 'Please provide updated source where route of measurement is noted. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:07:02
Query 'Please provide updated source where route of measurement is noted. ' answered with 'UPLOADED PER REQUEST' (Site from CRA).	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 14:35:20
User opened query 'Please provide updated source where route of measurement is noted. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:41:21
User closed query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:41:21
Query 'Please ensure route of measurement is documented in source. ' answered with 'noted' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:40:01
User opened query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:57:47
User entered 'Oral (Oral)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:57
User entered empty.	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:44
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User entered '084'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User entered 'bpm'	System	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:47
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 18:39:33
User entered '016'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User entered 'breaths/min'	System	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:53
User entered '144'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User entered 'mmHg'	System	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:40:55
User entered '100'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09
User entered 'mmHg'	System	10 Sep 2020 21:13:25

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09

US3752366

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:09

US3752366

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:59:08
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:14:11

US3752366

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:59:08
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:14:11

US3752366

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:21:23

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:59:17
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:15:03

US3752366

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:13:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:59:17
User entered '8 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:15:03

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:05:28

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:24
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
Query 'Per GCL Lab Recon: Saliva: Sample dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:05:48
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 07OCT2020 for COVID PCR Saliva is reported in PPD central lab, however sample details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:05:11
Query 'Per GCL Lab Recon: Saliva: Samples dated 22OCT2020 for Day 9, 28OCT2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva details are missing in EDC. Please complete, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:52
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 22OCT2020 for Day 9, 28OCT2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva details are missing in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:05:28

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:00:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 19:05:28

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:24
User entered 'SICKD28'	System	07 Oct 2020 19:05:28

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:02:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:02:18
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:02:20
User entered '13:20'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User entered '07 Oct 2020 13:20'	System	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:03:58
User entered '98.2' F	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:54:07
User closed query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:06:41
Query 'Please ensure route of measurement is documented in source. ' answered with 'confirmed' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 13:27:40
User opened query 'Please ensure route of measurement is documented in source. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:04:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:23
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:26
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User entered 'bpm'	System	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:28
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User entered 'breaths/min'	System	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered '114'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User entered 'mmHg'	System	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:32
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16
User entered 'mmHg'	System	07 Oct 2020 19:06:38

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:16

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:06:57

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:11
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:04:46
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:06:57

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:21:23

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 08:32:13
Query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'PER EPIP RESPONSE, VISIT 2 AND DAY 28 CONVALESCENT WERE COMBINED. SITE DID NOT HAVE DAY 28 KIT STOCKED THEREFORE UNSCHEDULED KIT WAS USED TO COLLECT SAMPLE. ' (Site from DM).	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:13:20
User opened query 'Per GCL Lab Reconciliation:Saliva: Sample dated 07OCT2020 is recorded under this visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:28:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:11:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:09:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 19:08:48

US3752366

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:21:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:14:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 10:48:03
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Unscheduled kits were all that were available. It was CV day 28' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	19 Jan 2021 16:43:27
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:23:07
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:04:54
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:11:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:09:40
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:08:48

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:33:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:28:54

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:33:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:28:54

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:33:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:28:54

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:28:54

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:07:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:02:50

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:07:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:02:50

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:01:50
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:01:50
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '1'	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'I'	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '180.3' cm	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '112.2' kg	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '34.51449'	System	14 Jan 2021 19:33:04
DataPoint set to visible.	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '180.3' cm	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '112.2' kg	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '34.51449'	System	14 Jan 2021 19:33:04
DataPoint set to visible.	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:19'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '14 Jan 2021 12:19'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '76'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'bpm'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'breaths/min'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '122'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '78'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '180.3' cm	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '112.2' kg	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '34.51449'	System	14 Jan 2021 19:33:04
DataPoint set to visible.	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '13:10'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '14 Jan 2021 13:10'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '72'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'bpm'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '18'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'breaths/min'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '125'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:36:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '70'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	14 Jan 2021 19:33:04

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:57

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:33:57

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mRNA-1273'	System	14 Jan 2021 19:34:21
DataPoint set to visible.	System	14 Jan 2021 19:29:24

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:40'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '14 Jan 2021 12:40'	System	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:37:56
User entered 'ONCE'	System	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 19:34:21

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:36

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:36

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:25'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:34:36

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '14 Jan 2021 12:25'	System	14 Jan 2021 19:34:36

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:35:53

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Collection 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	31 Mar 2021 19:25:35
User opened query 'Collection 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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:35:53

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:20'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:35:53

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '14 Jan 2021 12:20'	System	14 Jan 2021 19:35:53

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:35:43
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:36:08

US3752366

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '1'	System	14 Jan 2021 19:36:08

US3752366

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:07:33

US3752366

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '21 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	25 Jan 2021 19:07:33
	(b) (4)	

US3752366

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:07:33

US3752366

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:07:33

US3752366

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:07:39

US3752366

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'I'	System	25 Jan 2021 19:07:39

US3752366

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '1'	System	25 Jan 2021 19:07:39
DataPoint set to visible.	System	25 Jan 2021 19:07:39

US3752366

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:08

US3752366

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:08

US3752366

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:38:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:51:08

US3752366

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'OLD29'	System	09 Feb 2021 20:51:08

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:10'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '09 Feb 2021 12:10'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '67'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'bpm'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'breaths/min'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '130'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '86'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '13:00'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '09 Feb 2021 13:00'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '70'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'bpm'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'breaths/min'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '134'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '78'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mmHg'	System	09 Feb 2021 20:52:10

US3752366

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:23

US3752366

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:40:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:23

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'mRNA-1273'	System	09 Feb 2021 20:52:36
DataPoint set to visible.	System	25 Jan 2021 19:07:39

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
User opened query 'Start Date is after the Date of study discontinuation/completion on End of Study/Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:23:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '12:30'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '09 Feb 2021 12:30'	System	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:39
User entered 'ONCE'	System	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 20:52:36

US3752366

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:39:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:52:41

US3752366

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered '1'	System	09 Feb 2021 20:52:41

US3752366

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 23:36:49
	Amanda Horn (b) (4)	
	(b) (4)	

US3752366

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
User entered '19 Feb 2021'	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:36:49
	(b) (4)	

US3752366

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:36:49

US3752366

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:36:49
	(b) (4)	

US3752366

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
User entered 'Yes (Y)'	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:36:52
	(b) (4)	

US3752366

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:15:51
User entered 'I'	System	24 Feb 2021 23:36:52

US3752366

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:04:49

US3752366

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	22 Apr 2021 20:06:35
	Priyantha Wijewardane	08 Apr 2021 13:42:12
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'This date is correct because it was the only day the subject could come in. A deviation will be submitted.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:06:03
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Apr 2021 18:04:49
User entered '07 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 18:04:49

US3752366

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Clinic (Clinic)'	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:04:49

US3752366

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	07 Apr 2021 18:04:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '07 Apr 2021'	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '12:50'	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 12:50'	System	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
	(b) (4)	
User entered '98.1' F	(b) (4), (b) (6)	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Oral (Oral)'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered empty.	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '70'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '16'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '122'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '78'	(b) (4)	07 Apr 2021 18:06:49
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 18:06:49

US3752366

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 18:06:58

US3752366

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
	(b) (4)	
User entered '07 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 18:06:58

US3752366

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered 'Yes (Y)'	(b) (4)	07 Apr 2021 18:07:12
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
	(b) (4)	
User entered '07 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 18:07:12

US3752366

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:42:12
User entered '12:55'	(b) (4)	07 Apr 2021 18:07:12
	(b) (4), (b) (6)	

US3752366

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Apr 2021 12:55'	System	07 Apr 2021 18:07:12

US3752366

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:21:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:33:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 03:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 21:16:11
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:08:41

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:01
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 16:14:42

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'The Con-Med says Tylenol was taken for "SYMPTOMATIC COVID-19". Please update AE to match.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 21:44:06
User signature succeeded.	(b) (4), (b) (6)	08 Mar 2021 16:42:12
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:43:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 19:37:30
Data point term sent to Coder	(b) (4)	01 Feb 2021 19:37:30
Query 'The Con-Med says Tylenol was taken for "SYMPTOMATIC COVID-19". Please update AE to match.' answered with 'data changed' (Site from CRA).	System	01 Feb 2021 19:36:55
DataPoint Un-verified.	Jamie Pettus (b) (4)	01 Feb 2021 19:36:09
Coding entries removed.	(b) (4)	01 Feb 2021 19:35:57
User entered 'SYMPTOMATIC COVID-19' reason for change: Per Query Resolution	Jamie Pettus (b) (4)	01 Feb 2021 19:35:57
User opened query 'The Con-Med says Tylenol was taken for "SYMPTOMATIC COVID-19". Please update AE to match.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:53:39
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	(b) (4), (b) (6)	01 Dec 2020 20:06:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:10:22
Data point term sent to Coder	(b) (4)	23 Nov 2020 20:10:22
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 20:08:56
	System	23 Nov 2020 20:08:29

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Adverse event](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System). Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 20:08:29
User entered 'COVID-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 20:08:21
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:23:57
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 23:28:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 23:28:38
Data point term sent to Coder	System	11 Nov 2020 23:27:57
DataPoint Un-verified.	Amanda Horn (b) (4)	11 Nov 2020 23:27:23
Coding entries removed.	(b) (4)	11 Nov 2020 23:27:23
User entered 'SYMPTOMATIC COVID-19' reason for change: Per Query Resolution	Amanda Horn (b) (4)	11 Nov 2020 23:27:23
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' canceled (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:49:10
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:48:55
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:56:56

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:26:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:26:43
Query 'PV Query: Please update event term to COVID-19.' answered with 'updated' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:24
Data point term sent to Coder	System	15 Sep 2020 13:25:22
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:09
User entered 'COVID-19' reason for change: Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 13:25:09
User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:07:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:07:48
Data point term sent to Coder	System	10 Sep 2020 22:31:59
User entered 'CONFIRMED SYMPTOMATIC COVID-19 CASE'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Yes (Y)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'No (N)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Yes (Y)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:35
Query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' answered with 'data is correct' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:07:51
User opened query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:06:45
User closed query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:10:48
Query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' answered with 'COUGH, CHILLS, AND RHINORRHEA LISTED WITH START DATE 04SEP2020' (Site from Safety).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:17:19
User opened query 'PV Query: Please clarify event onset date. The date is listed as 04 Sep 2020 however, there are no symptoms or COVID test for that date. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:23
User entered '4 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Sep 2020 22:15:29
User entered '10 Sep 2020'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
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	10 Sep 2020 22:32:26
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	10 Sep 2020 22:32:26
	(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	10 Sep 2020 22:31:14
User entered '15:58'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:32:26
User entered '10 Sep 2020 15:58'	System	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 15:15:26
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:15:26
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 15:14:57
User entered 'Yes (Y)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide the event end date (date of resolution of symptoms).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:10:53
Query 'PV Query: Please provide the event end date (date of resolution of symptoms).' answered with '16SEP2020 IS THE FIRST DAY WITHOUT SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:15:59
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 15:14:57
User opened query 'PV Query: Please provide the event end date (date of resolution of symptoms).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:51:55
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'No (N)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Sep 2020 22:32:26
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		10 Sep 2020 22:32:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Sep 2020 22:31:14
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.		
	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4)	10 Sep 2020 22:32:26
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:34:32
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'SUBJECT IS A PHYSICIAN WHO HAD KNOWN EXPOSURE TO A COVID POSITIVE PATIENT ON 31AUG WHICH WAS 2 DAYS PRIOR TO V1 AND 5 DAYS PRIOR TO ONSET OF SYMPTOMS.' (Site from Safety).	Amanda Horn (b) (4)	07 Oct 2020 16:50:43
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4)	07 Oct 2020 16:50:36
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 15:15:52
User closed query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 20:18:18
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:41:20
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:41:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 19:41:20

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:25:53
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:24:57
Query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' answered with 'subject was exposed to someone with COVID on the monday prior to his first injection' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 19:23:32
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 19:22:35
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 19:22:35
User opened query 'PV Query: Please provide rationale for assessing the AE of COVID-19 as related to blinded study medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:09:48
User closed query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:03
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:20:51
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:20:51
Query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' answered with 'SUBJECT HAD KNOWN EXPOSURE TO A PATIENT WITH POSITIVE COVID 19 RESULTS 5 DAYS PRIOR TO DEVELOPING SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:19:56

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:19:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:19:09
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:18:05
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:18:05
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 15:14:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:14:57
User opened query 'PV Query: Please provide the investigator's causality assessment between the event and the study drug. As the subject received study drug, appropriate response would be related or not related.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:24
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:37:52
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:32:26
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:32:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Sep 2020 22:32:26
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 22:31:14

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 10:55:00
Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' answered with 'Subject did not receive additional doses.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:15:14
User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:49:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:37:14
Query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' answered with 'SUBJECT HAD KNOWN EXPOSURE TO A PATIENT WITH POSITIVE COVID 19 RESULTS 5 DAYS PRIOR TO DEVELOPING SYMPTOMS' (Site from DM).	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:19:09
User entered 'Related (RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:18:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 15:14:57

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: please review and reconcile Relationship to Study Procedure, since event started after first dose. Per CRF Completion Guidelines, Not Applicable is expected if clinical event is prior to first dose/investigational product.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:08:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Sep 2020 22:32:26
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
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) (4), (b) (6)	28 Oct 2020 20:10:02
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:10:00
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 'REASON FOR DOSING D/C IS DUE TO SUBJECT CONTRACTING COVID, THERE IS AN OPTION FOR THAT ON THE D/C MENU' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:15:13
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'SUBJECT WAS WITHDRAW FROM IP BUT IS CONTINUING IN THE STUDY WITH FUTURE VISITS' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:10:12
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	26 Oct 2020 17:02:42

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Oct 2020 00:35:32
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:34:45
User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:18:31
Query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' answered with 'SUBJECT RETURNED FOR V2 BUT IP NOT GIVEN. SUBJECT WILL CONTINUE OTHER STUDY VISITS' (Site from Safety).	Amanda Horn (b) (4)	07 Oct 2020 16:52:17

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' answered with 'SUBJECT RETURNED FOR V2 BUT IP NOT GIVEN. SUBJECT WILL CONTINUE OTHER STUDY VISITS' (Site from DM).	Amanda Horn (b) (4)	07 Oct 2020 16:52:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Amanda Horn (b) (4)	07 Oct 2020 16:51:59
User opened query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be "withdrawn" and second dosing not given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 15:16:24
User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 18:59:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 20:18:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:25:53
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:24:57
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. If patient will be receiving further IP doses, please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:16

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Action taken with investigational product

Audit	User	Time (GMT)
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. If patient will be receiving further IP doses, please update action taken to no change.' answered with 'SUBJECT WITH POSITIVE COVID RESULTS WILL NOT BE ELIGIBLE FOR DOSE 2 OF IP. ' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:20:00
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 15:14:57
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. If patient will be receiving further IP doses, please update action taken to no change.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:09
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amanda Horn (b) (4)	10 Sep 2020 22:37:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:13:31
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:32:09
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 22:45:10
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:45:02
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #2 recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:52:53
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:09:43
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:07:18
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:45:02
User closed query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:39:50
Query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:09:49
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:09:43
User opened query 'Per DM CLR - RQ: Site's response noted. However, this AE is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:29
Query 'Per DM CLR - RQ: Site's response noted. However, this is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:17
User opened query 'Per DM CLR - RQ: Site's response noted. However, this is not the CM indication. Please review and reconcile AE term and CM indication, so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:23:03

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:53:48
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'Subject began Tylenol 05SEP2020.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:17:09
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that is indicated for this AE. Please reconcile and update the Indication of the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'I'	Amanda Horn (b) (4) (b) (4)	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered '0'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:20
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with '16SEP2020 SUBJECT REPORTS RESOLUTION OF ALL SYMPTOMS' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:20:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:52:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

If outcome is [Recovered/Resolved with Sequelae](#), please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14
	(b) (4)	

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:30:55
User entered 'SUBJECT EXPOSED TO COVID POSITIVE PERSON THE MONDAY PRIOR TO FIRST DOSE. INVESTIGATIONAL PRODUCT WITHDRAWN' reason for change: Data Entry Error	Amanda Horn (b) (4)	07 Oct 2020 16:52:49
User closed query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:24:47
Query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' answered with 'began having symptoms on the 4th but wasn't seen in the clinic until the 8th therefore he didn't have telehealth visits at that time.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 21:31:45
User entered 'Subject exposed to COVID positive person the monday prior to first dose. 2nd dose of IP held' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 20:21:09
User opened query 'PV Query: Please fill out the COVID-19 assessment pages from 04-08 Sep 2020, as the subject began having COVID-19 symptoms on 04 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 13:09:33
User closed query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:12:00
User closed query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:55
User closed query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:51
User closed query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:11:33
Query 'PV Query: Please provide any additional 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).' answered with 'NO OTHER MEDICAL INTERVENTIONS OR SURGICAL TREATMENTS. THE ONLY CONCOMITANT MEDICATION WAS THE TYLENOL LISTED. ' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:14:53
Query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' answered with 'HE HAD KNOWN EXPOSURE ON 31 AUG. HE IS A FAMILY PHYSICIAN AND SAW THE PATIENT ON 31 AUG AND WAS NO AWARE OF THE POSITIVE RESULTS AT THE TIME OF HIS 1ST VISIT ON 02 SEP IN WHICH HE RECEIVED THE FIRST INJECTION.' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:13:48
Query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' answered with 'FEVER/CHILLS BEGAN 05 SEP' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:12:18
Query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' answered with 'ADDITIONAL TEST PERFORMED 08 SEP AT ILLNESS VISIT' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:11:11
Query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' answered with 'NEGATIVE BASELINE PCR RESULTS ON 02SEP2020' (Site from Safety).	Amanda Horn (b) (4)	21 Sep 2020 15:10:45

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:42
User opened query 'PV Query: Please confirm if the subject was experiencing fever/chills on 05 Sep (per the indication for Tylenol starting on 05 Sep).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:35
User opened query 'PV Query: Is this a baseline positive case or was an additional test performed on 08 Sep 2020? If test was collected around 08 Sep, please provide date test was performed along with date it resulted.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:54:06
User opened query 'PV Query: Please provide the results of the swab collected on 02 Sep 2020, along with the date it resulted.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:57
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 21:53:37
User entered empty.	Amanda Horn (b) (4)	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 22:31:14

US3752366

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:31:14

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:21:23

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:33:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per DM CLR: Per DM CLR - RQ: Site's response noted. However, Per Diary Dose 1 Day 4, Headache (General) Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 06:11:17
Query 'Per DM CLR: Per DM CLR - RQ: Site's response noted. However, Per Diary Dose 1 Day 4, Headache (General) Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'none listed per safety call follow up' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	02 Feb 2021 15:46:44
User opened query 'Per DM CLR: Per DM CLR - RQ: Site's response noted. However, Per Diary Dose 1 Day 4, Headache (General) Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 02:39:56
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:08:24

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:21:23

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:26:55
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	Amanda Horn (b) (4)	08 Nov 2020 19:23:28
User opened query 'Per DM CLR: Per Diary Dose 1 Day 4-5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:15:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:08:50

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 21:11:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 21:11:52
Data point term sent to Coder	System	03 Sep 2020 21:10:38
User entered 'Multivitamin'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:21:21
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Supplement'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '2 to 3 times per week'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'un UNK 2019'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:09:38

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 23:28:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:28:37
Data point term sent to Coder	System	11 Nov 2020 23:27:56
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:27:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
Data point term sent to Coder	System	08 Sep 2020 16:00:56
User entered 'TYLENOL'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:09:00
DataPoint Un-verified.	Amanda Horn (b) (4)	11 Nov 2020 23:27:40
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	(b) (4)	
User closed query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	Amanda Horn (b) (4)	11 Nov 2020 23:27:40
	(b) (4)	
User closed query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:22:11
Query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' answered with 'FEVER, CHILLS OCCURRED DAY 5 FOLLOWING INJECTION, DOES NOT MEET REPORTING CRITERIA' (Site from DM).	Amanda Horn (b) (4)	08 Nov 2020 19:20:51
	(b) (4)	
User opened query 'Per CDM: Thank you for your response. Please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria CD: please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:09:28

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:08:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' answered with 'Subjected noted chills in eDiary.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:20:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, CHILLS is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, CHILLS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:51:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'FEVER, CHILLS'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '1000'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	08 Nov 2020 19:20:47
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	08 Nov 2020 19:20:47
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	08 Nov 2020 19:20:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'once (ONCE)'	Amanda Horn (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered empty.	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per CDM: The start date of this Con med is not matching with the Diary dose 1, Temperature day logline #6. Kindly review and update the data as appropriate, else clarify. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:04:16
User entered '06 Sep 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	05 Feb 2021 19:13:17
Query 'Per CDM: The start date of this Con med is not matching with the Diary dose 1, Temperature day logline #6. Kindly review and update the data as appropriate, else clarify. Thankyou.' answered with 'This is how it was reported by the patient per follow-up phone call. He was called again and reported the diary entry was correct. data is corrected as a result' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	05 Feb 2021 19:12:51
User opened query 'Per CDM: The start date of this Con med is not matching with the Diary dose 1, Temperature day logline #6. Kindly review and update the data as appropriate, else clarify. Thankyou.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 06:10:09
User closed query 'Source indicates that start/stop date was on 05SEP2020--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:48:24
Query 'Source indicates that start/stop date was on 05SEP2020--please update EDC or clarify.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:17:07
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 18:16:59
User opened query 'Source indicates that start/stop date was on 05SEP2020--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:10:30
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:38
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:20:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:36:52

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered '0'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 19:13:17
User entered '05 Sep 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	02 Dec 2020 18:16:59
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	08 Nov 2020 19:20:47
DataPoint Un-verified.	System	08 Nov 2020 19:20:47
User entered '6 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	08 Nov 2020 19:20:47
User opened query 'End date is prior to start date. Please correct.' (Site from System).	Amanda Horn (b) (4)	08 Nov 2020 19:20:38
DataPoint Verified.	System	08 Nov 2020 19:20:38
User entered '5 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 18:36:52
	(b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:09:31
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:34:11
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'changed to no' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:12:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:12:04
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:52:27
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:09:57
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'changed' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:18:39
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:18:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:18:27

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:43:28
	(b) (4), (b) (6)	28 Oct 2020 18:36:52
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User entered empty.	System	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User entered empty.	System	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:11
User entered empty.	System	08 Sep 2020 16:00:41

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:29:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:29:38
Data point term sent to Coder	System	11 Nov 2020 23:28:58
Coding entries removed.	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:28:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:46:33
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 Nov 2020 11:46:33
Data point term sent to Coder	System	05 Nov 2020 16:43:30
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:11
User entered 'PROPHYLAXIS FOR SEASONAL INFLUENZA' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	11 Nov 2020 23:28:48
User entered 'Prophylaxix for seasonal influenza'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:13
User entered '0.5'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:17
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:19
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:24
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:30
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:37
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:38
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:40
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
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).	System	31 Mar 2021 19:25:35
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	31 Mar 2021 19:23:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:41
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:45
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User entered empty.	System	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User entered empty.	System	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:11:13
User entered empty.	System	05 Nov 2020 16:42:31

US3752366

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:21:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:39:18
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	24 Feb 2021 23:36:57
	(b) (4)	

US3752366

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:17:51
Query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' answered with 'UNSURE WHICH DATE TO USE. HE WAS NOT SEEN FOR V2 AS HE WAS COVID POSITIVE IN THE 28 DAYS FOLLOWING DOSE 1. DATE ENTERED REFLECTS DATE OF ILLNESS VISIT.' (Site from DM).	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:17:18
User entered '8 Sep 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	28 Oct 2020 15:17:14
User opened query 'Per CDM: Date of dose discontinuation does not match with any dose dates.Please reconcile, review and update or else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:29:06
User entered '16 Sep 2020'	(b) (4), (b) (6)	26 Oct 2020 17:02:42

US3752366

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 10:18:51
Query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 19:56:37
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	19 Nov 2020 19:56:04
User opened query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:49:45
User closed query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:35:12
Query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:48:50
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:48:38
User opened query 'Per CDM: AE #1 Covid-19 has IP withdrawn due to AE. If this AE was the reason for IP withdrawal then AE should be selected. Please clarify ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:25:15
User closed query 'Per CDM: AE #1 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:25:15
Query 'Per CDM: AE #1 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile' answered with 'SARS-COV-2 POSITIVE WITHIN 28 DAYS OF DOSE 1. WHICH WOULD BE APPROPRIATE TO CHOOSE? AE OR SARS-COV-2?' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Nov 2020 19:25:42
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:14:34

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	06 Nov 2020 18:12:24
reason for change: Data Entry Error		
User opened query 'Per CDM: AE #1 records Action	(b) (4), (b) (6)	06 Nov 2020 17:38:30
taken with investigational product as Investigational		
Product Withdrawn However, AE is not slecect as		
primary reason. Please reconcile' (Site from DM).		
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	26 Oct 2020 17:02:42

US3752366

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4)	19 Nov 2020 19:56:20
User entered empty; reason for change Data Entry Error	System	19 Nov 2020 19:56:20
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	Amanda Horn (b) (4)	19 Nov 2020 19:56:04
User entered 'COVID-19 contact' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:50:31
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:50:21
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:50:21
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:48:38
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:14:34
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	06 Nov 2020 18:12:24

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:02:42

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:52:12
Query 'Data is required. Please complete.' answered with 'data entered in error. Subject still continuing ' (Site from System).	Lauren Evans (b) (4)	31 Mar 2021 19:25:55
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:25:35
User entered empty; reason for change Data Entry Error	Lauren Evans (b) (4)	31 Mar 2021 19:25:35
User entered '08 Sep 2020'	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:52:13
Query 'Data is required. Please complete.' answered with 'data entered in error. subject still continuing' (Site from System).	Lauren Evans (b) (4)	31 Mar 2021 19:26:09
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:25:35
User entered empty; reason for change Data Entry Error	Lauren Evans (b) (4)	31 Mar 2021 19:25:35
User entered 'AE (specify) (ADVERSE EVENT)'	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User entered empty; reason for change Data Entry Error	(b) (4)	
	Lauren Evans (b) (4)	31 Mar 2021 19:25:35
User entered 'SARS- COV-2' reason for change: Data Entry Error	Lauren Evans (b) (4)	31 Mar 2021 19:24:03
User entered 'SARS- COVID-19'	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User entered empty.	(b) (4) Lauren Evans (b) (4)	31 Mar 2021 19:23:51

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

US3752366

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:35
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:28
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	31 Mar 2021 19:23:51

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:21:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '12/Sep/2020 12:16'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:21:23

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.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:21:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '16/Sep/2020 09:57'	System	16 Sep 2020 13:57:30

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:21:23

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.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:12:14
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 13:57:30

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:21:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '22/Sep/2020 11:12'	System	22 Sep 2020 15:12:27

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:21:23

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.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:24:57
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 15:12:27

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:21:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '30/Sep/2020 17:25'	System	30 Sep 2020 17:25:10

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:21:23

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.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:35:02
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 17:25:10

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered	System	12 Sep 2020 16:14:42
'USA-US113-2020-MRNA-1273-P301000001'		

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:16:16
User entered 'No (N)'	System	12 Sep 2020 16:14:42

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Priyantha'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'Wijewardane'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '9601 Baptist Health Dr Medical towers 1 Suite 310'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'Little Rock'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered 'AR'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
Amendment Manager: User entered empty.	System	14 Sep 2020 21:58:12
User entered '72209'	(b) (4), (b) (6)	14 Sep 2020 15:11:23

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:57:18
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:57:17
User entered 'US' (non-conformant).	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
User entered '5'	System	08 Oct 2020 13:35:22
User entered '4'	System	30 Sep 2020 17:25:10
User entered '3'	System	22 Sep 2020 15:12:27
User entered '2'	System	16 Sep 2020 13:57:30
User entered '1'	System	12 Sep 2020 16:16:21

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:21:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:43:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered '08/Oct/2020 13:35'	System	08 Oct 2020 13:35:22

US3752366

Folder: SAE USA-US113-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:21:23

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.	Priyantha Wijewardane	12 Feb 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 03:28:34
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 13:35:22