

US3752385 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:23:46

All time stamps listed in this document are displayed in GMT

US3752385

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Participant ID

US3752385

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

US3752385

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

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

Visit date (dd MMM yyyy)	03 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3752385

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3752385

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Date of Informed Consent (*dd MMM yyyy*) 03 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 19:45:46

Generated On: 12 Aug 2021 13:23:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3752385

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Condition	PENDULAR NYSTAGMUS
Start date (dd MMM yyyy)	(b) (6) 1988
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)	(b) (6) 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752385

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752385

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752385

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Condition	POLYCYSTIC OVARIAN SYNDROME
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3752385

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Condition	OBESITY
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)	

US3752385

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:15
Height (xxx.x)	62.5 in
Weight (xxx.x)	230.1 lb
BMI (xxx.x)	41.50176 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 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: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Date of assessment (dd MMM yyyy) 03 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	03 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:45:46

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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 19:45:46

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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 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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 19:45:46

Generated On: 12 Aug 2021 13:23:46

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 145659

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 19:45:46

Generated On: 12 Aug 2021 13:23:46

Height	ND - Not Done
Weight	ND - Not Done

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

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)	03 SEP 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:15
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 19:45:46

Generated On: 12 Aug 2021 13:23:46

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)	03 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 14:13

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

US3752385

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

13:52 (24 HR)

Collection date and time (derived)

03 SEP 2020 13:52

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	03 SEP 2020 13:50
Nasopharyngeal Swab 2	No		

US3752385

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:34

PC Open Date & Time

03 SEP 2020 14:33

PC Close Date & Time

03 SEP 2020 17:03

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 03 SEP 2020 17:58

PC Close Date & Time 04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:13

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

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

99.5 °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

06 SEP 2020 19:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 17:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

08 SEP 2020 17:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

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

98.0 °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

09 SEP 2020 16:39

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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

03 SEP 2020 14:34

PC Open Date & Time

03 SEP 2020 14:33

PC Close Date & Time

03 SEP 2020 17:03

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

03 SEP 2020 17:58

PC Close Date & Time

04 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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

04 SEP 2020 16:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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

05 SEP 2020 18:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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

06 SEP 2020 19:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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

07 SEP 2020 17:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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

08 SEP 2020 17:15

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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

09 SEP 2020 16:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 ☐

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:35
PC Open Date & Time	03 SEP 2020 14:33
PC Close Date & Time	03 SEP 2020 17:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 ☐

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 17:58

PC Close Date & Time

04 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

		Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 16:04	
PC Open Date & Time	04 SEP 2020 12:00	
PC Close Date & Time	05 SEP 2020 11:59	

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

		Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 18:14	
PC Open Date & Time	05 SEP 2020 12:00	
PC Close Date & Time	06 SEP 2020 11:59	

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

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

54 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

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

56 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

		Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 17:15	
PC Open Date & Time	07 SEP 2020 12:00	
PC Close Date & Time	08 SEP 2020 11:59	

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

		Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 17:15	
PC Open Date & Time	08 SEP 2020 12:00	
PC Close Date & Time	09 SEP 2020 11:59	

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:06
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3752385

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:39:40

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	VISIT2

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 12:19
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:45
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3752385

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 02 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 13:30 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 13:30

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

US3752385

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

12:30 (24 HR)

Collection date and time (derived)

02 OCT 2020 12:30

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:27	02 OCT 2020 12:27
Nasopharyngeal Swab 2	No		

US3752385

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:46

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 OCT 2020 13:50

PC Open Date & Time

02 OCT 2020 13:50

PC Close Date & Time

02 OCT 2020 16:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 OCT 2020 17:15

PC Close Date & Time

03 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 14:33

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	04 OCT 2020 18:43
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 OCT 2020 17:07

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 17:46

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

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

98.3 °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

07 OCT 2020 21:11

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

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

98.5 °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

08 OCT 2020 18:04

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 13:51

PC Open Date & Time

02 OCT 2020 13:50

PC Close Date & Time

02 OCT 2020 16:20

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

02 OCT 2020 17:15

PC Close Date & Time

03 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 14:30

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 18:44

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 17:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 17:46

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 21:08

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 OCT 2020 18:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 ☐

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:51
PC Open Date & Time	02 OCT 2020 13:50
PC Close Date & Time	02 OCT 2020 16:20

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 ☐

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 17:15

PC Close Date & Time

03 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 14:31
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:43
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

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

101 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:05
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

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

103 of 1902

EAB) (1725)

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:46
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 21:08
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 ☒

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 18:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3752385

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 12:17
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752385

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 NOV 2020

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

US3752385

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 NOV 2020

Collection time (00:00-23:59)

12:28 (24 HR)

Collection date and time (derived)

03 NOV 2020 12:28

US3752385

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:47

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 22:11:11
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 23:29:36

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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	01 DEC 2020 18:00:27
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 14:40:27
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 20:49:23

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Patient Cloud Open Date & Time	26 DEC 2020 00:01
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Patient Cloud Close Date & Time	30 DEC 2020 23:59
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US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 215

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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="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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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09 MAR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

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30 MAR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3752385

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.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

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.

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3752385

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 14 Mar 2021 18:12:20

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 14 Mar 2021 18:12:20

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

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

Visit date (dd MMM yyyy)	31 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 MAR 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 12:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 MAR 2021

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

US3752385

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

12:08 (24 HR)

Collection date and time (derived)

31 MAR 2021 12:08

US3752385

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 22:29:38

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 22:29:38

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752385

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:23:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752385

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3752385

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 18:39:40

Generated On: 12 Aug 2021 13:23:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 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>)	11 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

US3752385

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Height	
Weight	
BMI (xxx.x)	

US3752385

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 09:35
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3752385

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:35
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3752385

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3752385

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

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3752385

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 10:05

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

US3752385

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

09:48 (24 HR)

Collection date and time (derived)

11 JAN 2021 09:48

US3752385

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	09:50
Collection Date and Time (derived)	11 JAN 2021 09:50

US3752385

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752385

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:45:44

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3752385

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

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)	12 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 10:25
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

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 (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3752385

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Mar 2021 18:39:40

Generated On: 12 Aug 2021 13:23:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	12 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	10:35
Collection date and time (derived)	

US3752385

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

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)

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?

US3752385

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:41:43

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:40:12

Generated On: 12 Aug 2021 13:23:46

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

US3752385

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:40:12

Generated On: 12 Aug 2021 13:23:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752385

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:39:40

Generated On: 12 Aug 2021 13:23:46

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID OLD57

US3752385

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 19:45:43

Generated On: 12 Aug 2021 13:23:46

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

Yes ☒

No ☐

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

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication OCELLA

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTIVE

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

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication POLYCYSTIC OVARIAN SYNDROME

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 50

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication HEADACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	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)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication PRENATAL VITAMIN

Prophylaxis Yes ☐
No ☒

Indication PREGNANCY DIETARY 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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 500

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 17:32:34

Generated On: 12 Aug 2021 13:23:46

	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)	22 MAR 2021	
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"/>

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 11:24:59

Generated On: 12 Aug 2021 13:23:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 MAR 2021	TRANSVAGINAL ULTRASOUND	Diagnostic	
15 MAR 2021	PAP SMEAR	Diagnostic	

US3752385

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:23:46

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3752385 (Prod: Baptist Health Center for Clinical Research)

US3752385

Form: Participant Creation

Generated On: 12 Aug 2021 13:23:46

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:03:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'US3752385'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:59:44

US3752385

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:10:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:17:52

US3752385

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:10:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:59:46

US3752385

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[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 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:10:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:17:52

US3752385

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'SCRN'	System	03 Sep 2020 19:17:52

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered (b) (6) 1988'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:59:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '31'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'YEARS'	System	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '31'	System	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'l'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:30:47

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Sep 2020'	System	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2020'	System	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:02

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:59:46

US3752385

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'I'	System	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:12:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:23:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:12:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:06:05

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Coordination and balance disturbances, PT: Nystagmus, LLT: Nystagmus - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 07:12:58
Data point term sent to Coder	(b) (4)	
User entered 'Pendular nystagmus'	System	04 Sep 2020 20:07:59
	(b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User signature succeeded.	Priyantha Wijewardane	14 Apr 2021 17:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:28
User closed query 'per source, start year is 1988. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:09:22
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		13 Apr 2021 13:21:18
User entered (b) (6) 1988' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	13 Apr 2021 13:21:18
Query 'per source, start year is 1988. please review and clarify' answered with 'data updated' (Site from CRA).	Lauren Evans (b) (4)	12 Apr 2021 19:11:27
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	12 Apr 2021 19:11:06
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 19:11:06
User entered 'UN UNK 1988' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 19:11:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User opened query 'per source, start year is 1988. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:12:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	System	04 Sep 2020 20:07:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:07:59
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	04 Sep 2020 20:07:17
User entered 'un UNK 1988'	(b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User signature succeeded.	Priyantha Wijewardane	14 Apr 2021 17:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:28
DataPoint Un-verified.	Lauren Evans (b) (4)	12 Apr 2021 19:11:06
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 19:11:06
User entered '0' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 19:11:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:59
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered (b) (6) 1988'	System	13 Apr 2021 13:21:18
User entered 'Jan 1988'	System	12 Apr 2021 19:11:06
User entered empty.	System	04 Sep 2020 20:07:59
User entered 'Jan 1988'	System	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '1988'	System	12 Apr 2021 19:11:06
User entered empty.	System	04 Sep 2020 20:07:59
User entered '1988'	System	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:07:17

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 20:10:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:10:43
Data point term sent to Coder	System	04 Sep 2020 20:09:00
User entered 'Seasonal allergies'	(b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Jan 2018'	System	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2018'	System	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:08:16

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 20:10:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:10:42
Data point term sent to Coder	System	04 Sep 2020 20:09:03
User entered 'Migraine headaches'	(b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Jan 2016'	System	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2016'	System	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:08:39

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:10:42
Data point term sent to Coder	(b) (4)	
User entered 'Polycystic ovarian syndrome'	System	04 Sep 2020 20:09:03
	(b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'un UNK 2018' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:57:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:07:41
User entered 'un UNK 2018'	(b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:57:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:07:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Jan 2018'	System	05 Nov 2020 15:57:04
User entered empty.	System	05 Oct 2020 17:07:41
User entered 'Jan 2018'	System	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2018'	System	05 Nov 2020 15:57:04
User entered empty.	System	05 Oct 2020 17:07:41
User entered '2018'	System	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:09:01

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eye operation, LLT: Eye operation - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:11:03
Data point term sent to Coder	(b) (4)	
User entered 'Eye surgery'	System	04 Sep 2020 20:10:07
	(b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Jan 2000'	System	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2000'	System	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'Jan 2000'	System	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '2000'	System	04 Sep 2020 20:09:33

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
Query 'please provide source' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:17:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:21
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:16:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	02 Oct 2020 20:23:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 20:23:58
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 20:23:11
User entered 'Obesity'	(b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	02 Oct 2020 20:22:58

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '13:15'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '03 Sep 2020 13:15'	System	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '62.5' in	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13
DataPoint set to visible.	System	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '230.1' lb	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13
DataPoint set to visible.	System	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '41.50176'	System	04 Sep 2020 20:10:13
DataPoint set to visible.	System	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'kg/m2'	System	04 Sep 2020 20:10:13
DataPoint set to visible.	System	03 Sep 2020 19:18:06

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'bpm'	System	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'breaths/min'	System	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:17:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	04 Sep 2020 20:10:13

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40

US3752385

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40

US3752385

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:16:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:48:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:10:25

US3752385

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:16:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 14:48:29
User entered '03 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:10:25

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:10:40

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	04 Sep 2020 20:11:00

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'l'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:11:52

US3752385

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:05
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:06

US3752385

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:05
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:06

US3752385

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:05
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:06

US3752385

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'VISIT1'	System	04 Sep 2020 20:12:06

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:54:25

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User entered '145659'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:54:25

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:54:25

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

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)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:40

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

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)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:40

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:40

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:40

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:12:40

US3752385

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:46

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:22
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:15:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:15:07

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '13:15'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered '03 Sep 2020 13:15'	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:13:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:13:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:13:37
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:13:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'bpm'	System	04 Sep 2020 20:13:37
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:13:37
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:13:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'breaths/min'	System	04 Sep 2020 20:13:37
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:13:37
User entered '104' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:13:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'mmHg'	System	04 Sep 2020 20:13:37
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:13:37
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:13:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'mmHg'	System	04 Sep 2020 20:13:37
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '14:45' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered '03 Sep 2020 14:45'	System	04 Sep 2020 20:14:15
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:14:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'bpm'	System	04 Sep 2020 20:14:15
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'breaths/min'	System	04 Sep 2020 20:14:15
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'mmHg'	System	04 Sep 2020 20:14:15
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:19:59
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:14:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 20:14:15
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:13:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:13:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:56
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'mmHg'	System	04 Sep 2020 20:14:15
User entered empty.	System	04 Sep 2020 20:13:12

US3752385

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:05
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:14:22

US3752385

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:05
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:01:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:14:22

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:37:18
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:37:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:37:34
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 01:34:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:14:38

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:37:34
User entered '03 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:37:34
User entered 'Urine (URINE)'	(b) (4), (b) (6)	04 Sep 2020 20:14:38

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:37:34
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:35:44
Query 'per CDM: please select yes or no for this field answered with 'done' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 17:55:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 17:55:14
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 17:12:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:37:34
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:09
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered empty.	System	04 Sep 2020 20:14:38

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:18:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

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)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '14:13'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered '03 Sep 2020 14:13'	System	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:39
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'ONCE'	System	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:18:24

US3752385

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:48
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:14

US3752385

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:48
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:14

US3752385

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:48
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '13:52'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:14

US3752385

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered '03 Sep 2020 13:52'	System	04 Sep 2020 20:15:14

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '13:50'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered '03 Sep 2020 13:50'	System	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered empty.	System	04 Sep 2020 20:15:28

US3752385

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:20:56
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:33

US3752385

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'l'	System	04 Sep 2020 20:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:20', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0278b0e0-fa8a-422d-b858-508cd12e0ca6'	System	03 Sep 2020 19:34:52
User entered 'Yes (Y)'	System	03 Sep 2020 19:34:52

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:28', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0278b0e0-fa8a-422d-b858-508cd12e0ca6'	System	03 Sep 2020 19:34:52
User entered '98.2'	System	03 Sep 2020 19:34:52

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:31', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0278b0e0-fa8a-422d-b858-508cd12e0ca6'	System	03 Sep 2020 19:34:52
User entered 'No (N)'	System	03 Sep 2020 19:34:52

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0278b0e0-fa8a-422d-b858-508cd12e0ca6'	System	03 Sep 2020 19:34:52
User entered '03 Sep 2020 14:34'	System	03 Sep 2020 19:34:52

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 14:33'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:03'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:58'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 2'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:13:04', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '77c6b142-c833-49fc-ad17-6d19aded38f6'	System	04 Sep 2020 21:13:26
User entered 'Yes (Y)'	System	04 Sep 2020 21:13:26

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:13:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '77c6b142-c833-49fc-ad17-6d19aded38f6'	System	04 Sep 2020 21:13:26
User entered '98.6'	System	04 Sep 2020 21:13:26

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:13:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '77c6b142-c833-49fc-ad17-6d19aded38f6'	System	04 Sep 2020 21:13:26
User entered 'No (N)'	System	04 Sep 2020 21:13:26

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:13:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '77c6b142-c833-49fc-ad17-6d19aded38f6'	System	04 Sep 2020 21:13:26
User entered '04 Sep 2020 16:13'	System	04 Sep 2020 21:13:26

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 3'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:19:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '66756936-da1c-4137-9285-213c935d6e51'	System	05 Sep 2020 23:19:59
User entered 'Yes (Y)'	System	05 Sep 2020 23:19:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:19:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '66756936-da1c-4137-9285-213c935d6e51'	System	05 Sep 2020 23:19:59
User entered '99.0'	System	05 Sep 2020 23:19:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:19:50', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '66756936-da1c-4137-9285-213c935d6e51'	System	05 Sep 2020 23:19:59
User entered 'No (N)'	System	05 Sep 2020 23:19:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:19:55', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '66756936-da1c-4137-9285-213c935d6e51'	System	05 Sep 2020 23:19:59
User entered '05 Sep 2020 18:19'	System	05 Sep 2020 23:19:59

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 4'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:18', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c770ffe3-12e8-4d3a-93f6-4a64c9ab3b5f'	System	07 Sep 2020 00:01:39
User entered 'Yes (Y)'	System	07 Sep 2020 00:01:39

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c770ffe3-12e8-4d3a-93f6-4a64c9ab3b5f'	System	07 Sep 2020 00:01:39
User entered '99.5'	System	07 Sep 2020 00:01:39

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c770ffe3-12e8-4d3a-93f6-4a64c9ab3b5f'	System	07 Sep 2020 00:01:39
User entered 'No (N)'	System	07 Sep 2020 00:01:39

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c770ffe3-12e8-4d3a-93f6-4a64c9ab3b5f'	System	07 Sep 2020 00:01:39
User entered '06 Sep 2020 19:01'	System	07 Sep 2020 00:01:39

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 5'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:09', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'fa892ef1-0e57-478e-8b9b-5427d81f0b02'	System	07 Sep 2020 22:14:20
User entered 'Yes (Y)'	System	07 Sep 2020 22:14:20

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:14', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'fa892ef1-0e57-478e-8b9b-5427d81f0b02'	System	07 Sep 2020 22:14:20
User entered '98.8'	System	07 Sep 2020 22:14:20

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'fa892ef1-0e57-478e-8b9b-5427d81f0b02'	System	07 Sep 2020 22:14:20
User entered 'No (N)'	System	07 Sep 2020 22:14:20

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:19', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'fa892ef1-0e57-478e-8b9b-5427d81f0b02'	System	07 Sep 2020 22:14:20
User entered '07 Sep 2020 17:14'	System	07 Sep 2020 22:14:20

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 6'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:20:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '00b9f504-3527-4f76-9b93-d5a52bffc5d0'	System	08 Sep 2020 22:21:11
User entered 'Yes (Y)'	System	08 Sep 2020 22:21:11

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:21:03', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '00b9f504-3527-4f76-9b93-d5a52bffc5d0'	System	08 Sep 2020 22:21:11
User entered '97.5'	System	08 Sep 2020 22:21:11

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:21:06', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '00b9f504-3527-4f76-9b93-d5a52bffc5d0'	System	08 Sep 2020 22:21:11
User entered 'No (N)'	System	08 Sep 2020 22:21:11

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:21:09', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '00b9f504-3527-4f76-9b93-d5a52bffc5d0'	System	08 Sep 2020 22:21:11
User entered '08 Sep 2020 17:21'	System	08 Sep 2020 22:21:11

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 7'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:39:18', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ee7692f7-5eb4-46b5-a2f3-d941b8f35a0d'	System	09 Sep 2020 21:39:27
User entered 'Yes (Y)'	System	09 Sep 2020 21:39:27

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:39:22', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ee7692f7-5eb4-46b5-a2f3-d941b8f35a0d'	System	09 Sep 2020 21:39:27
User entered '98.0'	System	09 Sep 2020 21:39:27

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:39:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ee7692f7-5eb4-46b5-a2f3-d941b8f35a0d'	System	09 Sep 2020 21:39:27
User entered 'No (N)'	System	09 Sep 2020 21:39:27

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:39:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ee7692f7-5eb4-46b5-a2f3-d941b8f35a0d'	System	09 Sep 2020 21:39:27
User entered '09 Sep 2020 16:39'	System	09 Sep 2020 21:39:27

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bb7a6067-e425-4413-a4d2-2d1d96497836'	System	03 Sep 2020 19:34:57
User entered 'None (1)'	System	03 Sep 2020 19:34:57

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bb7a6067-e425-4413-a4d2-2d1d96497836'	System	03 Sep 2020 19:34:57
User entered 'No (N)'	System	03 Sep 2020 19:34:57

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bb7a6067-e425-4413-a4d2-2d1d96497836'	System	03 Sep 2020 19:34:57
User entered 'No (N)'	System	03 Sep 2020 19:34:57

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:52', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bb7a6067-e425-4413-a4d2-2d1d96497836'	System	03 Sep 2020 19:34:57
User entered 'None (1)'	System	03 Sep 2020 19:34:57

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:34:56', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bb7a6067-e425-4413-a4d2-2d1d96497836'	System	03 Sep 2020 19:34:57
User entered '03 Sep 2020 14:34'	System	03 Sep 2020 19:34:57

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 14:33'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:03'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:58'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 2'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:02:45', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '23425f15-cf55-4105-a830-684d59a9d511'	System	04 Sep 2020 21:03:12
User entered 'None (1)'	System	04 Sep 2020 21:03:12

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:02:51', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '23425f15-cf55-4105-a830-684d59a9d511'	System	04 Sep 2020 21:03:12
User entered 'No (N)'	System	04 Sep 2020 21:03:12

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:02:54', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '23425f15-cf55-4105-a830-684d59a9d511'	System	04 Sep 2020 21:03:12
User entered 'No (N)'	System	04 Sep 2020 21:03:12

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:06', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '23425f15-cf55-4105-a830-684d59a9d511'	System	04 Sep 2020 21:03:12
User entered 'None (1)'	System	04 Sep 2020 21:03:12

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '23425f15-cf55-4105-a830-684d59a9d511'	System	04 Sep 2020 21:03:12
User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:03:12

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 3'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:13:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2095d0c1-b683-4923-a4ef-cebb3631ba53'	System	05 Sep 2020 23:13:58
User entered 'None (1)'	System	05 Sep 2020 23:13:58

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:13:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2095d0c1-b683-4923-a4ef-cebb3631ba53'	System	05 Sep 2020 23:13:58
User entered 'No (N)'	System	05 Sep 2020 23:13:58

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:13:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2095d0c1-b683-4923-a4ef-cebb3631ba53'	System	05 Sep 2020 23:13:58
User entered 'No (N)'	System	05 Sep 2020 23:13:58

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:13:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2095d0c1-b683-4923-a4ef-cebb3631ba53'	System	05 Sep 2020 23:13:58
User entered 'None (1)'	System	05 Sep 2020 23:13:58

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:13:57', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2095d0c1-b683-4923-a4ef-cebb3631ba53'	System	05 Sep 2020 23:13:58
User entered '05 Sep 2020 18:13'	System	05 Sep 2020 23:13:58

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 4'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '341b2ad2-1fc0-4d25-8f5f-25c57c6bbc01'	System	07 Sep 2020 00:01:47
User entered 'None (1)'	System	07 Sep 2020 00:01:47

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '341b2ad2-1fc0-4d25-8f5f-25c57c6bbc01'	System	07 Sep 2020 00:01:47
User entered 'No (N)'	System	07 Sep 2020 00:01:47

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '341b2ad2-1fc0-4d25-8f5f-25c57c6bbc01'	System	07 Sep 2020 00:01:47
User entered 'No (N)'	System	07 Sep 2020 00:01:47

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:43', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '341b2ad2-1fc0-4d25-8f5f-25c57c6bbc01'	System	07 Sep 2020 00:01:47
User entered 'None (1)'	System	07 Sep 2020 00:01:47

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:45', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '341b2ad2-1fc0-4d25-8f5f-25c57c6bbc01'	System	07 Sep 2020 00:01:47
User entered '06 Sep 2020 19:01'	System	07 Sep 2020 00:01:47

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 5'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2bf8f38c-6598-4601-ad60-33aeb1742500'	System	07 Sep 2020 22:14:36
User entered 'None (1)'	System	07 Sep 2020 22:14:36

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:26', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2bf8f38c-6598-4601-ad60-33aeb1742500'	System	07 Sep 2020 22:14:36
User entered 'No (N)'	System	07 Sep 2020 22:14:36

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2bf8f38c-6598-4601-ad60-33aeb1742500'	System	07 Sep 2020 22:14:36
User entered 'No (N)'	System	07 Sep 2020 22:14:36

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:31', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2bf8f38c-6598-4601-ad60-33aeb1742500'	System	07 Sep 2020 22:14:36
User entered 'None (1)'	System	07 Sep 2020 22:14:36

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:14:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '2bf8f38c-6598-4601-ad60-33aeb1742500'	System	07 Sep 2020 22:14:36
User entered '07 Sep 2020 17:14'	System	07 Sep 2020 22:14:36

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 6'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:12', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd3371d1c-6350-4fa1-9d73-6c152b77f7d1'	System	08 Sep 2020 22:15:22
User entered 'None (1)'	System	08 Sep 2020 22:15:22

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:15', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd3371d1c-6350-4fa1-9d73-6c152b77f7d1'	System	08 Sep 2020 22:15:22
User entered 'No (N)'	System	08 Sep 2020 22:15:22

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd3371d1c-6350-4fa1-9d73-6c152b77f7d1'	System	08 Sep 2020 22:15:22
User entered 'No (N)'	System	08 Sep 2020 22:15:22

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:19', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd3371d1c-6350-4fa1-9d73-6c152b77f7d1'	System	08 Sep 2020 22:15:22
User entered 'None (1)'	System	08 Sep 2020 22:15:22

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:21', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd3371d1c-6350-4fa1-9d73-6c152b77f7d1'	System	08 Sep 2020 22:15:22
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 22:15:22

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 7'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'b07e26f0-2f6d-4950-b327-c43808164573'	System	09 Sep 2020 21:06:35
User entered 'None (1)'	System	09 Sep 2020 21:06:35

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'b07e26f0-2f6d-4950-b327-c43808164573'	System	09 Sep 2020 21:06:35
User entered 'No (N)'	System	09 Sep 2020 21:06:35

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:28', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'b07e26f0-2f6d-4950-b327-c43808164573'	System	09 Sep 2020 21:06:35
User entered 'No (N)'	System	09 Sep 2020 21:06:35

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:30', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'b07e26f0-2f6d-4950-b327-c43808164573'	System	09 Sep 2020 21:06:35
User entered 'None (1)'	System	09 Sep 2020 21:06:35

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:32', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'b07e26f0-2f6d-4950-b327-c43808164573'	System	09 Sep 2020 21:06:35
User entered '09 Sep 2020 16:06'	System	09 Sep 2020 21:06:35

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:07', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'None (0)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:16', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'None (0)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:21', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'None (0)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'None (0)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:28', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'None (0)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:34', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered 'No (N)'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-03T14:35:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '413fd019-b7b6-44d5-8038-b3321fd08266'	System	03 Sep 2020 19:35:49
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 19:35:49

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 14:33'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:03'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Sep 2020 17:58'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 2'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:21', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'None (0)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:37', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:43', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'None (0)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:46', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'None (0)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:49', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'None (0)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:03:54', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered 'No (N)'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-04T16:04:02', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f4ee0f82-c494-4c05-b142-55968612a1fc'	System	04 Sep 2020 21:04:03
User entered '04 Sep 2020 16:04'	System	04 Sep 2020 21:04:03

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 3'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:03', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:06', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:10', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:14', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:19', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:22', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'None (0)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered 'No (N)'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-05T18:14:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'c8014e41-686b-43f5-918e-38c855f22378'	System	05 Sep 2020 23:14:38
User entered '05 Sep 2020 18:14'	System	05 Sep 2020 23:14:38

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 4'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:49', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:52', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:55', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:57', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:01:59', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:02:02', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'None (0)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:02:07', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered 'No (N)'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-06T19:02:09', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac2471a9-863f-4a98-b719-59cd34e73837'	System	07 Sep 2020 00:02:10
User entered '06 Sep 2020 19:02'	System	07 Sep 2020 00:02:10

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 5'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'No interference with activity (1)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:14', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'None (0)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'None (0)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:20', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'None (0)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:22', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'None (0)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'None (0)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered 'No (N)'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-07T17:15:30', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4ce26e21-b6de-4605-8425-8881bf268fa7'	System	07 Sep 2020 22:15:33
User entered '07 Sep 2020 17:15'	System	07 Sep 2020 22:15:33

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 6'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:40', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'None (0)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:43', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'None (0)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:45', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'None (0)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'None (0)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:50', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'None (0)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:52', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered 'No (N)'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-08T17:15:55', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '7398c3dd-38bf-4039-83ac-5a856def0d7e'	System	08 Sep 2020 22:15:56
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 22:15:56

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 7'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:37', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:42', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'None (0)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:49', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered 'No (N)'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-09-09T16:06:52', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '89f6394f-ee9a-491d-afab-fd22d730036d'	System	09 Sep 2020 21:06:54
User entered '09 Sep 2020 16:06'	System	09 Sep 2020 21:06:54

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:18:24

US3752385

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:20
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:39

US3752385

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:20
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:39

US3752385

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:20
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:39

US3752385

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:33
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:20
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:39

US3752385

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:33:50

US3752385

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:23
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'l'	System	23 Sep 2020 18:33:50

US3752385

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:51
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:14

US3752385

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:51
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:14

US3752385

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:51
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:14

US3752385

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:51
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:34:14

US3752385

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:46
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:38
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:33:00

US3752385

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 17:02:38
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:18:30
User entered 'l'	System	02 Oct 2020 18:33:00

US3752385

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:02
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Mar 2021 18:32:20

US3752385

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:02
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered '24 Sep 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Mar 2021 18:32:20

US3752385

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:02
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Mar 2021 18:32:20

US3752385

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:02
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 18:32:20
	(b) (4)	

US3752385

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:33:08

US3752385

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'I'	System	02 Oct 2020 18:33:08

US3752385

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 18:33:52
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 18:33:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:33:39

US3752385

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 18:33:52
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:33:39

US3752385

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:33:39

US3752385

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'VISIT2'	System	02 Oct 2020 18:33:39

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '12:19'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:18
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:18
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:18
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:18
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'bpm'	System	02 Oct 2020 20:21:18
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:18
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:18
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'breaths/min'	System	02 Oct 2020 20:21:18
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:18
User entered '104' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:18
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	02 Oct 2020 20:21:18
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:18
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:18
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	02 Oct 2020 20:21:18
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:07:53
Query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' answered with 'Site miscalculated time vitals were to be obtained.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:20:29
User opened query 'Per CDM: Post-dose vital signs time is prior to or less than 30 minutes after the Dose Time. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:31:23
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 20:21:52
User entered '13:45' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '02 Oct 2020 13:45'	System	02 Oct 2020 20:21:52
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:52
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:21:52
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:52
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'bpm'	System	02 Oct 2020 20:21:52
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:52
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'breaths/min'	System	02 Oct 2020 20:21:52
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:52
User entered '108' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	02 Oct 2020 20:21:52
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 20:21:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Oct 2020 20:21:52
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:21:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:20:53
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	02 Oct 2020 20:21:52
User entered empty.	System	02 Oct 2020 20:20:53

US3752385

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:04

US3752385

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:04

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered empty.	System	02 Oct 2020 20:22:17

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

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)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '13:30'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '2 Oct 2020 13:30'	System	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:21:35
User entered 'ONCE'	System	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 18:34:32

US3752385

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:30

US3752385

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:30

US3752385

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '12:30'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:30

US3752385

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '02 Oct 2020 12:30'	System	02 Oct 2020 20:23:30

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '12:27'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '02 Oct 2020 12:27'	System	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered empty.	System	02 Oct 2020 20:23:45

US3752385

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:23:49

US3752385

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '1'	System	02 Oct 2020 20:23:49

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:50:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3460324a-c829-4903-8529-32b063334dd6'	System	02 Oct 2020 18:50:59
User entered 'Yes (Y)'	System	02 Oct 2020 18:50:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:50:50', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3460324a-c829-4903-8529-32b063334dd6'	System	02 Oct 2020 18:50:59
User entered '97.6'	System	02 Oct 2020 18:50:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:50:53', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3460324a-c829-4903-8529-32b063334dd6'	System	02 Oct 2020 18:50:59
User entered 'No (N)'	System	02 Oct 2020 18:50:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:50:57', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3460324a-c829-4903-8529-32b063334dd6'	System	02 Oct 2020 18:50:59
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 18:50:59

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 16:20'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 17:15'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 2'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:33:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd721fbf8-2301-44eb-be9f-5bbce5eb9580'	System	03 Oct 2020 19:33:37
User entered 'Yes (Y)'	System	03 Oct 2020 19:33:37

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:33:31', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd721fbf8-2301-44eb-be9f-5bbce5eb9580'	System	03 Oct 2020 19:33:37
User entered '97.5'	System	03 Oct 2020 19:33:37

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:33:35', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd721fbf8-2301-44eb-be9f-5bbce5eb9580'	System	03 Oct 2020 19:33:37
User entered 'No (N)'	System	03 Oct 2020 19:33:37

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:33:37', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd721fbf8-2301-44eb-be9f-5bbce5eb9580'	System	03 Oct 2020 19:33:37
User entered '03 Oct 2020 14:33'	System	03 Oct 2020 19:33:37

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 3'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:42:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c'	System	04 Oct 2020 23:43:20
User entered 'Yes (Y)'	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:42:53', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c' User entered '97.9'	System	04 Oct 2020 23:43:20
	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:42:57', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c'	System	04 Oct 2020 23:43:20
User entered 'Yes (Y)'	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
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 'Site will confirm with subject and update EDC/Source accordingly.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 10:12:13
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).	(b) (4), (b) (6)	05 Oct 2020 15:42:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c'	System	04 Oct 2020 23:43:20
User entered '1'	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c' User entered '0'	System	04 Oct 2020 23:43:20
	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'f120d477-a55c-45d0-952a-6082cdf7734c'	System	04 Oct 2020 23:43:20
User entered '04 Oct 2020 18:43'	System	04 Oct 2020 23:43:20

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 4'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:06:03', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'adc39cc5-d06b-48f9-9d90-d9715c47ea93'	System	05 Oct 2020 22:07:49
User entered 'Yes (Y)'	System	05 Oct 2020 22:07:49

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:06:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'adc39cc5-d06b-48f9-9d90-d9715c47ea93'	System	05 Oct 2020 22:07:49
User entered '98.6'	System	05 Oct 2020 22:07:49

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:07:35', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'adc39cc5-d06b-48f9-9d90-d9715c47ea93'	System	05 Oct 2020 22:07:49
User entered 'No (N)'	System	05 Oct 2020 22:07:49

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:07:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'adc39cc5-d06b-48f9-9d90-d9715c47ea93'	System	05 Oct 2020 22:07:49
User entered '05 Oct 2020 17:07'	System	05 Oct 2020 22:07:49

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 5'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:19', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '08233297-4251-4b33-ac88-a83652b419ca'	System	06 Oct 2020 22:46:29
User entered 'Yes (Y)'	System	06 Oct 2020 22:46:29

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:22', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '08233297-4251-4b33-ac88-a83652b419ca'	System	06 Oct 2020 22:46:29
User entered '99.2'	System	06 Oct 2020 22:46:29

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '08233297-4251-4b33-ac88-a83652b419ca'	System	06 Oct 2020 22:46:29
User entered 'No (N)'	System	06 Oct 2020 22:46:29

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:26', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '08233297-4251-4b33-ac88-a83652b419ca'	System	06 Oct 2020 22:46:29
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 22:46:29

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 6'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:11:26', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'cb76b82d-054e-4b99-b2f5-cf25c613a066'	System	08 Oct 2020 02:11:39
User entered 'Yes (Y)'	System	08 Oct 2020 02:11:39

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:11:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'cb76b82d-054e-4b99-b2f5-cf25c613a066'	System	08 Oct 2020 02:11:39
User entered '98.3'	System	08 Oct 2020 02:11:39

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:11:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'cb76b82d-054e-4b99-b2f5-cf25c613a066'	System	08 Oct 2020 02:11:39
User entered 'No (N)'	System	08 Oct 2020 02:11:39

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:11:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'cb76b82d-054e-4b99-b2f5-cf25c613a066'	System	08 Oct 2020 02:11:39
User entered '07 Oct 2020 21:11'	System	08 Oct 2020 02:11:39

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 7'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:57', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4c275320-10e5-4246-a880-5857b1718db7'	System	08 Oct 2020 23:04:53
User entered 'Yes (Y)'	System	08 Oct 2020 23:04:53

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:04:40', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4c275320-10e5-4246-a880-5857b1718db7'	System	08 Oct 2020 23:04:53
User entered '98.5'	System	08 Oct 2020 23:04:53

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:04:42', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4c275320-10e5-4246-a880-5857b1718db7'	System	08 Oct 2020 23:04:53
User entered 'No (N)'	System	08 Oct 2020 23:04:53

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:04:49', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4c275320-10e5-4246-a880-5857b1718db7'	System	08 Oct 2020 23:04:53
User entered '08 Oct 2020 18:04'	System	08 Oct 2020 23:04:53

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:03', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bfe75a2d-f38e-4e86-915b-2f653cad73a7'	System	02 Oct 2020 18:51:14
User entered 'None (1)'	System	02 Oct 2020 18:51:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:05', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bfe75a2d-f38e-4e86-915b-2f653cad73a7'	System	02 Oct 2020 18:51:14
User entered 'No (N)'	System	02 Oct 2020 18:51:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:08', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bfe75a2d-f38e-4e86-915b-2f653cad73a7'	System	02 Oct 2020 18:51:14
User entered 'No (N)'	System	02 Oct 2020 18:51:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bfe75a2d-f38e-4e86-915b-2f653cad73a7'	System	02 Oct 2020 18:51:14
User entered 'None (1)'	System	02 Oct 2020 18:51:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'bfe75a2d-f38e-4e86-915b-2f653cad73a7'	System	02 Oct 2020 18:51:14
User entered '02 Oct 2020 13:51'	System	02 Oct 2020 18:51:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 16:20'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 17:15'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 2'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'a463fc37-4e17-425b-8c2f-30ff027b57a1'	System	03 Oct 2020 19:30:29
User entered 'None (1)'	System	03 Oct 2020 19:30:29

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'a463fc37-4e17-425b-8c2f-30ff027b57a1'	System	03 Oct 2020 19:30:29
User entered 'No (N)'	System	03 Oct 2020 19:30:29

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:16', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'a463fc37-4e17-425b-8c2f-30ff027b57a1'	System	03 Oct 2020 19:30:29
User entered 'No (N)'	System	03 Oct 2020 19:30:29

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'a463fc37-4e17-425b-8c2f-30ff027b57a1'	System	03 Oct 2020 19:30:29
User entered 'None (1)'	System	03 Oct 2020 19:30:29

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:28', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'a463fc37-4e17-425b-8c2f-30ff027b57a1'	System	03 Oct 2020 19:30:29
User entered '03 Oct 2020 14:30'	System	03 Oct 2020 19:30:29

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 3'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:44:03', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd4306715-0e72-4fb2-b15b-e4816e3955bc'	System	04 Oct 2020 23:44:14
User entered 'None (1)'	System	04 Oct 2020 23:44:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:44:05', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd4306715-0e72-4fb2-b15b-e4816e3955bc'	System	04 Oct 2020 23:44:14
User entered 'No (N)'	System	04 Oct 2020 23:44:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:44:07', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd4306715-0e72-4fb2-b15b-e4816e3955bc'	System	04 Oct 2020 23:44:14
User entered 'No (N)'	System	04 Oct 2020 23:44:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:44:10', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd4306715-0e72-4fb2-b15b-e4816e3955bc'	System	04 Oct 2020 23:44:14
User entered 'None (1)'	System	04 Oct 2020 23:44:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:44:12', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd4306715-0e72-4fb2-b15b-e4816e3955bc'	System	04 Oct 2020 23:44:14
User entered '04 Oct 2020 18:44'	System	04 Oct 2020 23:44:14

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 4'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:37', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '94279e50-44db-4595-8cf8-4ded514894fd'	System	05 Oct 2020 22:05:54
User entered 'None (1)'	System	05 Oct 2020 22:05:54

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '94279e50-44db-4595-8cf8-4ded514894fd'	System	05 Oct 2020 22:05:54
User entered 'No (N)'	System	05 Oct 2020 22:05:54

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:42', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '94279e50-44db-4595-8cf8-4ded514894fd'	System	05 Oct 2020 22:05:54
User entered 'No (N)'	System	05 Oct 2020 22:05:54

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:46', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '94279e50-44db-4595-8cf8-4ded514894fd'	System	05 Oct 2020 22:05:54
User entered 'None (1)'	System	05 Oct 2020 22:05:54

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '94279e50-44db-4595-8cf8-4ded514894fd'	System	05 Oct 2020 22:05:54
User entered '05 Oct 2020 17:05'	System	05 Oct 2020 22:05:54

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 5'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '50c3acad-2567-4d20-956b-44d90147cd80'	System	06 Oct 2020 22:46:39
User entered 'None (1)'	System	06 Oct 2020 22:46:39

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:31', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '50c3acad-2567-4d20-956b-44d90147cd80'	System	06 Oct 2020 22:46:39
User entered 'No (N)'	System	06 Oct 2020 22:46:39

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '50c3acad-2567-4d20-956b-44d90147cd80'	System	06 Oct 2020 22:46:39
User entered 'No (N)'	System	06 Oct 2020 22:46:39

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:35', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '50c3acad-2567-4d20-956b-44d90147cd80'	System	06 Oct 2020 22:46:39
User entered 'None (1)'	System	06 Oct 2020 22:46:39

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '50c3acad-2567-4d20-956b-44d90147cd80'	System	06 Oct 2020 22:46:39
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 22:46:39

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 6'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:04', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '5a4f1c20-090f-4d9b-b429-8b8a20bd9179'	System	08 Oct 2020 02:08:16
User entered 'None (1)'	System	08 Oct 2020 02:08:16

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:06', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '5a4f1c20-090f-4d9b-b429-8b8a20bd9179'	System	08 Oct 2020 02:08:16
User entered 'No (N)'	System	08 Oct 2020 02:08:16

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:08', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '5a4f1c20-090f-4d9b-b429-8b8a20bd9179'	System	08 Oct 2020 02:08:16
User entered 'No (N)'	System	08 Oct 2020 02:08:16

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:09', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '5a4f1c20-090f-4d9b-b429-8b8a20bd9179'	System	08 Oct 2020 02:08:16
User entered 'None (1)'	System	08 Oct 2020 02:08:16

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:12', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '5a4f1c20-090f-4d9b-b429-8b8a20bd9179'	System	08 Oct 2020 02:08:16
User entered '07 Oct 2020 21:08'	System	08 Oct 2020 02:08:16

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 7'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:30', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ebec17f6-4194-4c57-b1ba-1f35a045c654'	System	08 Oct 2020 23:02:42
User entered 'None (1)'	System	08 Oct 2020 23:02:42

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:34', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ebec17f6-4194-4c57-b1ba-1f35a045c654'	System	08 Oct 2020 23:02:42
User entered 'No (N)'	System	08 Oct 2020 23:02:42

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:37', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ebec17f6-4194-4c57-b1ba-1f35a045c654'	System	08 Oct 2020 23:02:42
User entered 'No (N)'	System	08 Oct 2020 23:02:42

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ebec17f6-4194-4c57-b1ba-1f35a045c654'	System	08 Oct 2020 23:02:42
User entered 'None (1)'	System	08 Oct 2020 23:02:42

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ehec17f6-4194-4c57-b1ba-1f35a045c654'	System	08 Oct 2020 23:02:42
User entered '08 Oct 2020 18:02'	System	08 Oct 2020 23:02:42

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'None (0)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'No interference with activity (1)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'None (0)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:31', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'None (0)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'None (0)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'None (0)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:40', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered 'No (N)'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-02T13:51:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '605c88ad-af60-4aa2-91c2-965996e90eac'	System	02 Oct 2020 18:51:45
User entered '02 Oct 2020 13:51'	System	02 Oct 2020 18:51:45

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 16:20'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '02 Oct 2020 17:15'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 2'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:34', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:46', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:50', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:51', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:53', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'None (0)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:30:56', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered 'No (N)'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-03T14:31:08', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ade25f8b-e940-479c-81a0-2855141f2aca'	System	03 Oct 2020 19:31:10
User entered '03 Oct 2020 14:31'	System	03 Oct 2020 19:31:10

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 3'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'None (0)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:47', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'None (0)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:49', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'None (0)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:51', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'None (0)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:55', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered 'No (N)'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-04T18:43:59', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '87f3ce6e-80c5-4008-8b55-73e3b8799152'	System	04 Oct 2020 23:44:01
User entered '04 Oct 2020 18:43'	System	04 Oct 2020 23:44:01

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 4'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:14', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:18', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:20', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:22', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:25', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'None (0)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:30', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered 'No (N)'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-05T17:05:33', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '668bcb2d-c4eb-44a0-8e23-9447f29defc5'	System	05 Oct 2020 22:05:36
User entered '05 Oct 2020 17:05'	System	05 Oct 2020 22:05:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 5'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:39', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:41', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:43', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:44', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:46', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:48', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'None (0)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:51', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered 'No (N)'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-06T17:46:53', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '51d10442-a810-4d7b-9824-66d522092b58'	System	06 Oct 2020 22:46:58
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 22:46:58

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 6'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:17', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'No interference with activity (1)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:19', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'None (0)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:21', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'None (0)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'None (0)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'None (0)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:26', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'None (0)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:30', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered 'No (N)'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-07T21:08:32', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'd53bd6b4-4f28-4279-86e6-b8737ecee6a4'	System	08 Oct 2020 02:08:36
User entered '07 Oct 2020 21:08'	System	08 Oct 2020 02:08:36

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	02 Oct 2020 18:34:32
User entered 'Day 7'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:04', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:06', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:09', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:13', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:16', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'None (0)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:18', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered 'No (N)'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-10-08T18:02:20', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '3d8ef216-c3e1-49c3-8325-e6db6d9f7262'	System	08 Oct 2020 23:02:23
User entered '08 Oct 2020 18:02'	System	08 Oct 2020 23:02:23

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:34:32

US3752385

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:23:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:34:32

US3752385

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:12:18

US3752385

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:12:18

US3752385

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:12:18

US3752385

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:12:18

US3752385

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Oct 2020 21:53:09

US3752385

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'I'	System	18 Oct 2020 21:53:09

US3752385

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Oct 2020 21:53:23

US3752385

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '16 Oct 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Oct 2020 21:53:23

US3752385

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Oct 2020 21:53:23

US3752385

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:34
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	18 Oct 2020 21:53:23
	(b) (4)	

US3752385

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	18 Oct 2020 21:53:27

US3752385

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'I'	System	18 Oct 2020 21:53:27

US3752385

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:09:40

US3752385

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:09:40

US3752385

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:09:40

US3752385

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:09:40

US3752385

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:54:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:09:46

US3752385

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'I'	System	23 Oct 2020 14:09:46

US3752385

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:57:51

US3752385

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:57:51

US3752385

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:23:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:57:51

US3752385

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'VISIT3'	System	05 Nov 2020 15:57:51

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '12:17'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '03 Nov 2020 12:17'	System	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'bpm'	System	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'breaths/min'	System	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '110'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'mmHg'	System	05 Nov 2020 15:58:17

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52

US3752385

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52

US3752385

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:26

US3752385

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:24:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:26

US3752385

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:43

US3752385

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:43

US3752385

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:26:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered '12:28'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:43

US3752385

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '03 Nov 2020 12:28'	System	05 Nov 2020 15:58:43

US3752385

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:26:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:58:48

US3752385

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered '1'	System	05 Nov 2020 15:58:48

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 64'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had 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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-04T22:11:05', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4df9d73f-ae76-4db6-8fb6-626e84108ab3'	System	05 Nov 2020 04:11:15
User entered 'No (N)'	System	05 Nov 2020 04:11:15

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Have you been exposed to someone with known SARS-CoV-2 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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-04T22:11:08', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4df9d73f-ae76-4db6-8fb6-626e84108ab3'	System	05 Nov 2020 04:11:15
User entered 'No (N)'	System	05 Nov 2020 04:11:15

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-04T22:11:11', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '4df9d73f-ae76-4db6-8fb6-626e84108ab3'	System	05 Nov 2020 04:11:15
User entered '04 Nov 2020 22:11:11'	System	05 Nov 2020 04:11:15

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 71'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had 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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-11T23:29:29', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0d7173e9-5d2e-4c2f-aabf-fb36b4fa4475'	System	12 Nov 2020 05:29:40
User entered 'No (N)'	System	12 Nov 2020 05:29:40

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Have you been exposed to someone with known SARS-CoV-2 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 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-11T23:29:32', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0d7173e9-5d2e-4c2f-aabf-fb36b4fa4475'	System	12 Nov 2020 05:29:40
User entered 'No (N)'	System	12 Nov 2020 05:29:40

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-11-11T23:29:36', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0d7173e9-5d2e-4c2f-aabf-fb36b4fa4475'	System	12 Nov 2020 05:29:40
User entered '11 Nov 2020 23:29:36'	System	12 Nov 2020 05:29:40

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:04:01
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57
Data entry locked.	System	03 Sep 2020 19:18:24
User entered 'Day 78'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:18:24

US3752385

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:45:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:27:57
Data entry locked.	System	03 Sep 2020 19:18:24
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:18:24

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had 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 (3e297a792d64283e)', Time: '2020-12-01T18:00:21', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'becf9522-0c81-4c43-8441-0aa952854bc6'	System	02 Dec 2020 00:00:31
User entered 'No (N)'	System	02 Dec 2020 00:00:31

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you been exposed to someone with known SARS-CoV-2 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 (3e297a792d64283e)', Time: '2020-12-01T18:00:24', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'becf9522-0c81-4c43-8441-0aa952854bc6'	System	02 Dec 2020 00:00:31
User entered 'No (N)'	System	02 Dec 2020 00:00:31

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-12-01T18:00:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'becf9522-0c81-4c43-8441-0aa952854bc6'	System	02 Dec 2020 00:00:31
User entered '01 Dec 2020 18:00:27'	System	02 Dec 2020 00:00:31

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had 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 (3e297a792d64283e)', Time: '2020-12-08T14:40:20', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0b0d7769-6785-427d-bdae-6f0c031d5d5d'	System	08 Dec 2020 20:40:29
User entered 'No (N)'	System	08 Dec 2020 20:40:29

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you been exposed to someone with known SARS-CoV-2 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 (3e297a792d64283e)', Time: '2020-12-08T14:40:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0b0d7769-6785-427d-bdae-6f0c031d5d5d'	System	08 Dec 2020 20:40:29
User entered 'No (N)'	System	08 Dec 2020 20:40:29

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-12-08T14:40:27', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: '0b0d7769-6785-427d-bdae-6f0c031d5d5d'	System	08 Dec 2020 20:40:29
User entered '08 Dec 2020 14:40:27'	System	08 Dec 2020 20:40:29

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Have you had 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 (3e297a792d64283e)', Time: '2020-12-16T20:47:43', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac27b6ef-5857-4568-8d61-ea6aca3e7774'	System	17 Dec 2020 02:49:25
User entered 'No (N)'	System	17 Dec 2020 02:49:25

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

Have you been exposed to someone with known SARS-CoV-2 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 (3e297a792d64283e)', Time: '2020-12-16T20:49:12', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac27b6ef-5857-4568-8d61-ea6aca3e7774'	System	17 Dec 2020 02:49:25
User entered 'No (N)'	System	17 Dec 2020 02:49:25

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3e297a792d64283e)', Time: '2020-12-16T20:49:23', User OID: 'PatientReportedOutcome (US3752385)', ODM File OID: 'ac27b6ef-5857-4568-8d61-ea6aca3e7774'	System	17 Dec 2020 02:49:25
User entered '16 Dec 2020 20:49:23'	System	17 Dec 2020 02:49:25

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:27:57

US3752385

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:27:57
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:27:57

US3752385

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:23:52

US3752385

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:23:52

US3752385

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:23:52

US3752385

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:23:52

US3752385

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:23:56

US3752385

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:11:52
User entered 'I'	System	24 Nov 2020 16:23:56

US3752385

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Dec 2020 15:27:34

US3752385

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '28 Dec 2020'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Dec 2020 15:27:34

US3752385

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Dec 2020 15:27:34

US3752385

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Dec 2020 15:27:34

US3752385

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Dec 2020 15:27:37

US3752385

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
User entered 'I'	System	29 Dec 2020 15:27:37

US3752385

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Jan 2021 15:08:38

US3752385

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '27 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Jan 2021 15:08:38

US3752385

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Jan 2021 15:08:38

US3752385

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Jan 2021 15:08:38

US3752385

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	29 Jan 2021 15:08:41

US3752385

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
User entered 'I'	System	29 Jan 2021 15:08:41

US3752385

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:31
User signature succeeded.	Priyantha Wijewardane	14 Mar 2021 18:12:20
Signature has been broken.	(b) (4) Jamie Pettus (b) (4)	12 Mar 2021 20:10:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jamie Pettus (b) (4)	12 Mar 2021 20:10:41
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:42:16
Query 'Data is required. Please complete.' answered with 'it hasn't been long enough' (Site from System).	Jamie Pettus (b) (4)	26 Feb 2021 19:59:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	24 Feb 2021 23:43:58
User entered 'Yes (Y)'	Amanda Horn (b) (4)	24 Feb 2021 23:43:58
	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:42:52
	(b) (4)	

US3752385

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:31
User signature succeeded.	Priyantha Wijewardane	14 Mar 2021 18:12:20
Signature has been broken.	(b) (4) Jamie Pettus (b) (4)	12 Mar 2021 20:10:41
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) Jamie Pettus (b) (4)	12 Mar 2021 20:10:41
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:40:12
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Feb 2021 23:43:58
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	24 Feb 2021 23:43:58
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:43:58
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Feb 2021 23:42:52
User entered '12 Feb 2021'	Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:42:52

US3752385

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:31
User signature succeeded.	Priyantha Wijewardane	14 Mar 2021 18:12:20
Signature has been broken.	(b) (4)	12 Mar 2021 20:10:41
User entered 'Contact Made (CONTACT MADE)'	Jamie Pettus (b) (4)	12 Mar 2021 20:10:41
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered empty; reason for change Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:43:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:42:52
	(b) (4)	

US3752385

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:31
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:42:52

US3752385

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:39
User signature succeeded.	Priyantha Wijewardane	14 Mar 2021 18:12:20
User entered 'Yes (Y)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 20:10:47

US3752385

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:57:35
User entered '1'	System	12 Mar 2021 20:10:47

US3752385

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:34:45
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 17:55:05
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:34:45
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '31 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 17:55:05

US3752385

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:34:45
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Clinic (Clinic)'	Haylee Rowe (b) (4)	31 Mar 2021 17:55:05

US3752385

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 17:55:05

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 17:55:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '31 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:55:40
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '12:00'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:55:40
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:00'	System	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '97.9' F	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Oral (Oral)'	(b) (4)	31 Mar 2021 17:55:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 17:55:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '79'	Haylee Rowe (b) (4)	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '16'	Haylee Rowe (b) (4)	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '120'	(b) (4)	31 Mar 2021 17:55:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:12
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '72'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:55:40
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 17:55:40

US3752385

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 17:55:50
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '31 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:55:50
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:37
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 17:56:02

US3752385

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:37
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '31 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:56:02
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:37
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '12:08'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:56:02
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:08'	System	31 Mar 2021 17:56:02

US3752385

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:35:41
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 17:56:05
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 17:56:05

US3752385

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:38
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	30 Apr 2021 16:07:19
	(b) (4)	

US3752385

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:38
	(b) (4)	
User entered '30 Apr 2021'	Timothy Campbell (b) (4)	30 Apr 2021 16:07:19
	(b) (4)	

US3752385

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	30 Apr 2021 16:07:19
	(b) (4)	

US3752385

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:38
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	30 Apr 2021 16:07:19
	(b) (4)	

US3752385

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	30 Apr 2021 22:29:38
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	30 Apr 2021 16:07:24
	(b) (4)	

US3752385

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 16:07:24

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:22:48

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:22:48

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[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 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Clinic (Clinic)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:22:48

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 17:22:48

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

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 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered '0'	(b) (4) Haylee Rowe (b) (4)	24 Mar 2021 14:40:03
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:13:34

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	Haylee Rowe (b) (4)	24 Mar 2021 14:40:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:13:34

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Placebo (Placebo)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:08:16
User entered 'Placebo (Placebo)'	Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:08:16
User entered 'Placebo (Placebo)'	Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:27:39
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '1'	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'I'	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	11 Jan 2021 17:24:38
DataPoint set to visible.	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	11 Jan 2021 17:24:38
DataPoint set to visible.	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User accepted default value 'Pre-Dose (PREDOSE)'	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '09:35'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '11 Jan 2021 09:35'	System	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '98.1' F	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (Oral)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '78'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'bpm'	System	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '14'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'breaths/min'	System	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '118'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '84'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:24:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	11 Jan 2021 17:24:38
DataPoint set to visible.	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User accepted default value 'Post-Dose (POSTDOSE)'	Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '10:35'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '11 Jan 2021 10:35'	System	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '98.1' F	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (Oral)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '74'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'bpm'	System	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '15'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'breaths/min'	System	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '120'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:28:58
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '80'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mmHg'	System	11 Jan 2021 17:25:38

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:26:19

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:26:19

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Urine (URINE)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Negative (NEGATIVE)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User closed query 'Per CDM: Was FSH sample collected is recorded as 'No', however Collection date and time are provided. Please review and update accordingly.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:26:28
' (Site from DM).		
Query 'Per CDM: Was FSH sample collected is recorded as 'No', however Collection date and time are provided. Please review and update accordingly.	Jamie Pettus (b) (4) (b) (4)	18 Jan 2021 20:49:50
' answered with 'data changed' (Site from DM).		
User opened query 'Per CDM: Was FSH sample collected is recorded as 'No', however Collection date and time are provided. Please review and update accordingly.	(b) (4), (b) (6)	15 Jan 2021 12:57:10
' (Site from DM).		
User entered 'No (N)'	Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	18 Jan 2021 20:49:43
	(b) (4)	
User entered '11 Jan 2021'	Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	18 Jan 2021 20:49:43
	(b) (4)	
User entered '10:00'	Tonya Cato (b) (4)	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered empty.	System	18 Jan 2021 20:49:43
User entered '11 Jan 2021 10:00'	System	11 Jan 2021 17:29:27

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

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 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'mRNA-1273'	System	11 Jan 2021 17:33:56
DataPoint set to visible.	System	11 Jan 2021 17:23:18

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '10:05'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '11 Jan 2021 10:05'	System	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:11
User entered 'ONCE'	System	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 17:33:56

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:34:47

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:34:47

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '09:48'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:34:47

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '11 Jan 2021 09:48'	System	11 Jan 2021 17:34:47

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:35:10

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '11 Jan 2021'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:35:10

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '09:50'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:35:10

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered '11 Jan 2021 09:50'	System	11 Jan 2021 17:35:10

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:29:37
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	11 Jan 2021 17:35:25

US3752385

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:40
User entered 'I'	System	11 Jan 2021 17:35:25

US3752385

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Jan 2021 20:54:09

US3752385

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '18 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Jan 2021 20:54:09

US3752385

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Jan 2021 20:54:09

US3752385

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	19 Jan 2021 20:54:09
	(b) (4)	

US3752385

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	19 Jan 2021 20:54:12

US3752385

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'I'	System	19 Jan 2021 20:54:12

US3752385

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered '1'	System	19 Jan 2021 20:54:12
DataPoint set to visible.	System	19 Jan 2021 20:54:12

US3752385

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:31:28
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:57:12

US3752385

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:31:28
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '12 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:57:12

US3752385

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:31:28
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Clinic (Clinic)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:57:12

US3752385

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'OLD29'	System	12 Feb 2021 19:57:12

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User accepted default value 'Pre-Dose (PREDOSE)'	Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '12 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '10:25'	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered '12 Feb 2021 10:25'	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '97.1' F	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Oral (Oral)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '81'	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'bpm'	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '16'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'breaths/min'	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '112'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'mmHg'	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '74'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'mmHg'	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User accepted default value 'Post-Dose (POSTDOSE)'	Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:20
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:58:29
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:58:29

US3752385

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:26
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:50

US3752385

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:26
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered '12 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:58:50

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered '12 Feb 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered 'Urine (URINE)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:09:41
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy test at site is positive. A pregnancy form will be submitted ASAP.' (Site from System).	Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 20:00:35
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	12 Feb 2021 19:59:20
User entered 'Positive (POSITIVE)'	Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
Signature has been broken.	(b) (4)	24 Mar 2021 14:40:32
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	24 Mar 2021 14:40:32
User signature succeeded.	(b) (4)	06 Mar 2021 00:40:12
User closed query 'Per CDM, Was FSH sample collected is recorded as 'No'. However, data is provided. Please review and update accordingly	Priyantha Wijewardane	23 Feb 2021 13:53:09
' (Site from DM).	(b) (4)	
Query 'Per CDM, Was FSH sample collected is recorded as 'No'. However, data is provided. Please review and update accordingly	(b) (4), (b) (6)	22 Feb 2021 19:51:47
' answered with 'corrected' (Site from DM).	Jamie Pettus (b) (4)	22 Feb 2021 19:51:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM, Was FSH sample collected is recorded as 'No'. However, data is provided. Please review and update accordingly	(b) (4), (b) (6)	17 Feb 2021 17:38:57
' (Site from DM).		
User entered 'No (N)'	Haylee Rowe (b) (4)	12 Feb 2021 19:59:20
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
Signature has been broken.	(b) (4)	24 Mar 2021 14:40:32
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	24 Mar 2021 14:40:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered '12 Feb 2021'	(b) (4)	12 Feb 2021 19:59:20
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:33
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered '10:35'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	24 Mar 2021 14:40:32
User entered '12 Feb 2021 10:35'	System	12 Feb 2021 19:59:20

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'No (N)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Pregnancy (PREGNANCY)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:59:45
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:59:45
DataPoint set to visible.	System	19 Jan 2021 20:54:12

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:59:45
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	12 Feb 2021 19:59:45
	(b) (4)	

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:53
User entered empty.	System	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered empty.	System	12 Feb 2021 19:59:45

US3752385

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:32:59
User signature succeeded.	Priyantha Wijewardane	19 Feb 2021 14:41:43
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	12 Feb 2021 19:59:51

US3752385

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:08
User entered 'I'	System	12 Feb 2021 19:59:51

US3752385

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:44:21

US3752385

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered '19 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:44:21

US3752385

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:44:21

US3752385

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:32
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 23:44:21
	(b) (4)	

US3752385

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:35
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 23:44:25

US3752385

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:51:25
User entered 'I'	System	24 Feb 2021 23:44:25

US3752385

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:33:07
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered 'No (N)'	(b) (4)	
	Haylee Rowe (b) (4)	24 Mar 2021 14:41:24
	(b) (4)	

US3752385

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:33:07
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered empty.	(b) (4)	24 Mar 2021 14:41:24
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:33:07
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:39:40
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	24 Mar 2021 14:41:24
	(b) (4)	

US3752385

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	24 Mar 2021 14:41:24

US3752385

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:23:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:36:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:43

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:23:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:40:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:36:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:15:49

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: DROSPIRENONE;ETHINYLESTRADIOL, PRODUCTSYNONYM: OCELLA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:17:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:17:40
Data point term sent to Coder	System	04 Sep 2020 20:17:19
User entered 'Ocella'	(b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 20:24:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Contraceptive'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'l'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:00
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4)	31 Mar 2021 18:01:00
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
User entered '1'	System	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
User entered '1'	System	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:46
User entered '804 (804)'	System	04 Sep 2020 20:16:23

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 20:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:18:18
Data point term sent to Coder	System	04 Sep 2020 20:17:19
User entered 'Metformin'	(b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Polycystic ovarian syndrome'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '500'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
User signature succeeded.	Priyantha Wijewardane	14 Apr 2021 17:32:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:26
User closed query 'per source, year is 2018. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:08:24
Query 'per source, year is 2018. please review and clarify' answered with 'data updated per query' (Site from CRA).	Lauren Evans (b) (4)	12 Apr 2021 19:09:02
Signature has been broken.	Lauren Evans (b) (4)	12 Apr 2021 19:08:35
User entered 'UN UNK 2018' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Apr 2021 19:08:35
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:33
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User opened query 'per source, year is 2018. please review and clarify' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:38:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 07:59:54
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:07:58
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:30:37
User entered 'un UNK 2017'	(b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:23
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
User entered '1'	System	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
User entered '1'	System	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:49
User entered '804 (804)'	System	04 Sep 2020 20:17:08

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 20:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:19:45
Data point term sent to Coder	System	04 Sep 2020 20:19:21
User entered 'Amitriptyline'	(b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Migraine headaches'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '50'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:40
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:01:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
User entered '1'	System	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
User entered '1'	System	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:16:50
User entered '804 (804)'	System	04 Sep 2020 20:18:46

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 20:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:19:45
Data point term sent to Coder User entered 'Claritin'	System (b) (4), (b) (6)	04 Sep 2020 20:19:22 04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Seasonal allergies'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:45:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:19:12

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 18:07:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:07:10
Data point term sent to Coder	System	31 Mar 2021 18:05:37
User entered 'MAGNESIUM'	Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'HEADACHES'	Haylee Rowe (b) (4)	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '400'	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'mg (mg)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:04:40
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Oral (ORAL)'	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '22 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:04:40
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '0'	Haylee Rowe (b) (4)	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'No (N)'	(b) (4)	31 Mar 2021 18:04:40
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 18:04:40

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 07:08:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 07:08:33
Data point term sent to Coder	System	31 Mar 2021 18:05:37
User entered 'PRENATAL VITAMIN'	Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'No (N)'	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'PREGNANCY DIETARY SUPPLEMENT'	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'I'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'tablet (TABLET)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'once daily (QD)'	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Oral (ORAL)'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '12 Feb 2021'	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '0'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:05:32
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'No (N)'	(b) (4)	31 Mar 2021 18:05:32
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 18:05:32

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 18:08:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:08:12
Data point term sent to Coder	System	31 Mar 2021 18:06:38
User entered 'TYLENOL EXTRA STRENGTH'	Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'No (N)'	(b) (4)	31 Mar 2021 18:06:31
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'HEADACHES'	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '500'	(b) (4)	31 Mar 2021 18:06:31
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'mg (mg)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'as needed (PRN)'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:06:31
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Oral (ORAL)'	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '22 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '0'	Haylee Rowe	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Yes (Y)'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 18:06:31
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:18
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'No (N)'	Haylee Rowe (b) (4)	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:06:31

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:23:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:40:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:40:43
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:56:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:56:56
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:40:12
	(b) (4)	
User entered 'No (N)'	Amanda Horn (b) (4)	24 Feb 2021 23:44:31
	(b) (4)	

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:23:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '15 Mar 2021'	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:58:39
	(b) (4)	

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:23:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'TRANSVAGINAL ULTRASOUND'	Haylee Rowe (b) (4)	31 Mar 2021 17:58:39

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe (b) (4)	31 Mar 2021 17:58:39

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:23:46

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	31 Mar 2021 17:58:39
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:23:46

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered '15 Mar 2021'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 17:59:24

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:23:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'PAP SMEAR'	(b) (4) Haylee Rowe (b) (4) (b) (4)	31 Mar 2021 17:59:24

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:23:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered 'Diagnostic (DIAGNOSTIC)'	Haylee Rowe (b) (4)	31 Mar 2021 17:59:24

US3752385

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:23:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:43:05
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:24:59
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	31 Mar 2021 17:59:24
	(b) (4)	