

US3752088 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:25:13

All time stamps listed in this document are displayed in GMT

US3752088

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

[Participant ID](#)

US3752088

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

US3752088

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

Visit date (dd MMM yyyy)	14 AUG 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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US3752088

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:21:55

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3752088

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:21:56

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Condition	DEVIATED SEPTUM REPAIR
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Condition	IVP DYE ALLERGY
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)	

US3752088

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Condition	IBUPROFEN ALLERGY
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)	

US3752088

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Condition	INTERMITTENT HEADACHES
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3752088

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:00
Height (<i>xxx.x</i>)	74.0 in
Weight (<i>xxx.x</i>)	230.1 lb
BMI (<i>xxx.x</i>)	29.60486 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:21:56

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:21:56

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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 True

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 18:21:56

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104115

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 18:21:56

Generated On: 12 Aug 2021 13:25:13

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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)	14 AUG 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:00
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 18:21:56

Generated On: 12 Aug 2021 13:25:13

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)	14 AUG 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 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 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

09:37 (24 HR)

Collection date and time (derived)

14 AUG 2020 09:37

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	14 AUG 2020 09:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 10:38

PC Open Date & Time

14 AUG 2020 10:25

PC Close Date & Time

14 AUG 2020 12:55

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 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	14 AUG 2020 17:38
PC Open Date & Time	14 AUG 2020 13:50
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

98.0 °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

15 AUG 2020 17:35

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 18:13

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

98.2 °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

17 AUG 2020 18:06

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 00:36

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 18:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

98.2 °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

20 AUG 2020 17:49

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

14 AUG 2020 10:38

PC Open Date & Time

14 AUG 2020 10:25

PC Close Date & Time

14 AUG 2020 12:55

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:39

PC Open Date & Time

14 AUG 2020 13:50

PC Close Date & Time

15 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

15 AUG 2020 17:35

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

16 AUG 2020 18:13

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

17 AUG 2020 18:06

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

19 AUG 2020 00:36

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

19 AUG 2020 18:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

20 AUG 2020 17:49

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 10:38
PC Open Date & Time	14 AUG 2020 10:25
PC Close Date & Time	14 AUG 2020 12:55

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:39
PC Open Date & Time	14 AUG 2020 13:50
PC Close Date & Time	15 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 ☒

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:35
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

51 of 2237

EAB) (1725)

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:14
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

53 of 2237

EAB) (1725)

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:07
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

55 of 2237

EAB) (1725)

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 00:37
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

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EAB) (1725)

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 ☒

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:50
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3752088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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 SEP 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:36
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:55
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3752088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

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) 11 SEP 2020

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

Treatment Date and Time (derived) 11 SEP 2020 11:23

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

US3752088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

10:50 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:50

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:48	11 SEP 2020 10:48
Nasopharyngeal Swab 2	No		

US3752088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

98.0 °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

11 SEP 2020 11:44

PC Open Date & Time

11 SEP 2020 11:43

PC Close Date & Time

11 SEP 2020 14:13

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 96.6 °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	12 SEP 2020 06:46
PC Open Date & Time	11 SEP 2020 15:08
PC Close Date & Time	12 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

13 SEP 2020 06:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 13:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

15 SEP 2020 18:11

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

97.6 °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

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:17

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

11 SEP 2020 11:44

PC Open Date & Time

11 SEP 2020 11:43

PC Close Date & Time

11 SEP 2020 14:13

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 06:46

PC Open Date & Time

11 SEP 2020 15:08

PC Close Date & Time

12 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

13 SEP 2020 06:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

13 SEP 2020 13:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

14 SEP 2020 12:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

15 SEP 2020 18:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

16 SEP 2020 12:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

17 SEP 2020 12:17

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:45
PC Open Date & Time	11 SEP 2020 11:43
PC Close Date & Time	11 SEP 2020 14:13

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 06:46
PC Open Date & Time	11 SEP 2020 15:08
PC Close Date & Time	12 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 06:04
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 ☒

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 ☒

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EAB) (1725)

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

		Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 18:13	
PC Open Date & Time	15 SEP 2020 12:00	
PC Close Date & Time	16 SEP 2020 11:59	

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 ☒

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:17
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3752088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:35 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 07:35
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3752088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

07:41 (24 HR)

Collection date and time (derived)

16 OCT 2020 07:41

US3752088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:56

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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	14 OCT 2020 06:49:24
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

21 OCT 2020 18:49:11

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 04:34:15

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 05:28:16

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 03:34:05
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 04:41:05
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 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	06 DEC 2020 05:12:54
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 00:06:56
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 02:42:04

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 03:34:02

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 05:33:49

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 05:13:04

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 07:07:21
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:55:52

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 18:31:38

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 05:24:25

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 FEB 2021 20:08:28
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 04:28:56

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 05:07:53

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 18:59:37

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 18:21:05

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 13:39:15

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 12:06:04

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 06:39:52

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 06:04:25

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 06:54:03

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 06:01:37

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 10:27:31

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐
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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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°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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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°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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐ 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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐ 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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐ 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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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°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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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°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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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="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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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°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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐
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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐ 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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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 ☐

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3752088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:25:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 05:08:06

US3752088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

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

Visit date (dd MMM yyyy)	17 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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US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 11:19:03

Generated On: 12 Aug 2021 13:25:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 07:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3752088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

07:38 (24 HR)

Collection date and time (derived)

17 MAR 2021 07:38

US3752088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752088

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:25:13

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"/>

US3752088

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:25:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752088

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

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

Visit date (dd MMM yyyy)	12 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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US3752088

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 13:06:59

Generated On: 12 Aug 2021 13:25:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3752088

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Height	187.9 cm
Weight	107.4 kg
BMI (xxx.x)	30.41941

US3752088

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Height	187.9 cm
Weight	107.4 kg
BMI (xxx.x)	30.41941
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 JAN 2021
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 09:35
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)	65 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)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3752088

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Height	187.9 cm
Weight	107.4 kg
BMI (xxx.x)	30.41941
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)	12 JAN 2021
Time of assessment (00:00-23:59)	10:43 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:43
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3752088

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

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3752088

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

Form: Exposure

Data signed: (b) (4) 17 Mar 2021 20:25:50

Generated On: 12 Aug 2021 13:25:13

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 10:13 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 10:13

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

US3752088

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

09:49 (24 HR)

Collection date and time (derived)

12 JAN 2021 09:49

US3752088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00 - 23:59)	09:47
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Collection Date and Time (derived)	12 JAN 2021 09:47
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US3752088

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3752088

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	08:58 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 08:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

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	

US3752088

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3752088

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

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?

US3752088

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:36:04

Generated On: 12 Aug 2021 13:25:13

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT DECLINED INJECTION
2 AT OL-D29, NO SAFETY CALL
ATTEMPTED

If Contact Not Made, please provide Comments

US3752088

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:36:04

Generated On: 12 Aug 2021 13:25:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752088

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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 _____

US3752088

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

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.

US3752088

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3752088

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Mar 2021 00:24:50

Generated On: 12 Aug 2021 13:25:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	RIGHT EAR HEARING LOSS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	VOMITTING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID

Adverse event

LOW GRADE FEVER

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 20 Mar 2021 01:28:48

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:21:55

Generated On: 12 Aug 2021 13:25:13

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

Yes ☒

No ☐

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

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT HEADACHE

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 (1)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

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

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication SEASONAL INFLUENZA
VACCINATION

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF SEASONAL
INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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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) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication PPSV23

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PNEUMONIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	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)		01 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"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR HEARING LOSS

Dose per administration 10

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 (5)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRATYMPANIC
Start date (dd MMM yyyy)	03 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR HEARING LOSS

Dose per administration 10

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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US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRATYMPANIC
Start date (dd MMM yyyy)	10 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR HEARING LOSS

Dose per administration 60

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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US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	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)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 FEB 2021		
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"/>

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR HEARING LOSS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	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)	18 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	20 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR HEARING LOSS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 10 Apr 2021 14:04:26

Generated On: 12 Aug 2021 13:25:13

	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)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 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"/>

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Mar 2021 20:25:49

Generated On: 12 Aug 2021 13:25:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 11:19:03

Generated On: 12 Aug 2021 13:25:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 JAN 2021	HYPERBARIC CHAMBER- 38 HOURS OF TREATMENT	Adverse Event	
12 MAR 2021	COVID-19 PCR TEST- NEGATIVE	Adverse Event	
03 FEB 2021	DEXAMETHASONE PERFUSION RIGHT EAR	Adverse Event	
10 FEB 2021	DEXAMETHASONE PERFUSION RIGHT EAR	Adverse Event	

US3752088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:25:13

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

US3752088 (Prod: Baptist Health Center for Clinical Research)

US3752088

Form: Participant Creation

Generated On: 12 Aug 2021 13:25:13

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:29:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'US3752088'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:30

US3752088

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:09

US3752088

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:30
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:31

US3752088

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 15:36:09

US3752088

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'SCRN'	System	14 Aug 2020 15:36:09

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:38
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:32

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:40
User entered '64'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'YEARS'	System	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '64'	System	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:41
User entered 'Male (M)'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:44
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:55:40

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'Aug 2020'	System	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '2020'	System	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:36:22

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:38:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:31

US3752088

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'I'	System	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:25:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:56:11

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:58:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:58:17
Data point term sent to Coder	System	17 Aug 2020 16:57:26
User entered 'Deviated septum repair'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User entered 'un UNK 1995'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User entered 'un UNK 1995'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:39:58
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'Jan 1995'	System	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '1995'	System	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'Jan 1995'	System	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '1995'	System	17 Aug 2020 16:56:37

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User closed query 'Please consider documenting condition as "Right Elbow Reconstruction" ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:05:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:29:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:29:48
Query 'Please consider documenting condition as "Right Elbow Reconstruction" ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:49:41
Data point term sent to Coder	System	14 Sep 2020 14:48:22
Coding entries removed.	(b) (4), (b) (6)	14 Sep 2020 14:48:15
User entered 'Right elbow reconstruction' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:48:15
User opened query 'Please consider documenting condition as "Right Elbow Reconstruction" ' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:41:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 11:16:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 11:16:07
Data point term sent to Coder	System	17 Aug 2020 16:58:29
User entered 'Elbow reconstruction on the right'	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 22:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 22:44:34
User entered 'No (N)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	31 Aug 2020 22:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 16:57:33
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:05:13
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:33

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:59:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:59:22
Data point term sent to Coder	System	17 Aug 2020 16:58:31
User entered 'Right knee meniscus repair'	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 16:58:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 16:58:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:58:14
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 16:57:59
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:15
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:57:59

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Parathyroid gland therapeutic procedures, PT: Parathyroidectomy, LLT: Parathyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 17:01:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 17:01:56
Data point term sent to Coder	System	17 Aug 2020 16:59:32
User entered 'Parathyroidectomy'	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:21
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:32

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Hip surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:59:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:59:18
Data point term sent to Coder	System	17 Aug 2020 16:59:32
User entered 'Right total hip surgery'	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:27
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	17 Aug 2020 16:58:54

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:23:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Contrast media allergy, LLT: Allergy to intravenous contrast media - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 12:00:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 12:00:31
Data point term sent to Coder	System	16 Oct 2020 18:44:18
User entered 'IVP DYE allergy' reason for change:	(b) (4), (b) (6)	16 Oct 2020 18:43:55
Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:43:27
User entered 'IVP dye'	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:23:53
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:23:54
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:23:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:23:58
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:24:00
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:27

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:24:03
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 07:31:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 07:31:57
Data point term sent to Coder	System	16 Oct 2020 18:44:17
User entered 'Ibuprofen allergy'	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:05
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:07
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:24:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:12
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:24:14
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:43:40

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:20:51
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:45:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:45:37
Data point term sent to Coder	System	27 Oct 2020 14:45:00
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 14:44:33
User entered 'INTERMITTENT HEADACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:44:33
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 07:46:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 07:46:15
Data point term sent to Coder	System	16 Oct 2020 18:48:28
User entered 'Headache'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:36:43
User closed query 'The source indicates a start date of Unk/Unk/ 2020. Please verify and update if agreed.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 18:36:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
Query 'The source indicates a start date of Unk/Unk/ 2020. Please verify and update if agreed.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 21:28:00
User entered 'un UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 21:27:53
User opened query 'The source indicates a start date of Unk/Unk/ 2020. Please verify and update if agreed.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 16:20:47
User closed query 'Start date is after date of Informed System Consent. Please correct.' (Site from System).		16 Oct 2020 18:48:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:48:26
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	16 Oct 2020 18:47:57
User entered '28 Aug 2020'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:36:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	28 Dec 2020 21:28:06
DataPoint Un-verified.	System	28 Dec 2020 21:28:06
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 21:28:06
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 21:27:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:20:54
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:48:26
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:20:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:48:47
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:20:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:48:47
User entered '28 Aug 2020'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:20:59
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'Jan 2020'	System	28 Dec 2020 21:27:53
User entered empty.	System	16 Oct 2020 18:48:26
User entered 'Aug 2020'	System	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '2020'	System	28 Dec 2020 21:27:53
User entered empty.	System	16 Oct 2020 18:48:26
User entered '2020'	System	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:48:47
User entered 'Aug 2020'	System	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered empty.	System	16 Oct 2020 18:48:47
User entered '2020'	System	16 Oct 2020 18:47:57

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:46
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:48
User entered '09:00'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '14 Aug 2020 09:00'	System	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:49
User entered '74.0' in	(b) (4), (b) (6)	17 Aug 2020 16:59:48
DataPoint set to visible.	System	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:41:51
User entered '230.1' lb	(b) (4), (b) (6)	17 Aug 2020 16:59:48
DataPoint set to visible.	System	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
Amendment Manager: User entered '29.60486'	System	16 Sep 2020 23:56:52
User entered '29.6'	System	17 Aug 2020 16:59:48
DataPoint set to visible.	System	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'kg/m2'	System	17 Aug 2020 16:59:48
DataPoint set to visible.	System	14 Aug 2020 15:36:27

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:24:45
User closed query 'Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please consider updating VS values to ND and recording the values on Visit 1 Day 1 page.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:39:14
Query 'Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please consider updating VS values to ND and recording the values on Visit 1 Day 1 page.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 16:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:34:58
User opened query 'Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please consider updating VS values to ND and recording the values on Visit 1 Day 1 page.' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:42:10
User entered '98.3' F	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:34:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	14 Sep 2020 16:34:58
change Data Entry Error		
User entered '54'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'bpm'	System	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	14 Sep 2020 16:34:58
change Data Entry Error		
User entered '15'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'breaths/min'	System	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	14 Sep 2020 16:34:58
change Data Entry Error		
User entered '126'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'mmHg'	System	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:24:45
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	14 Sep 2020 16:34:58
change Data Entry Error		
User entered '86'	(b) (4), (b) (6)	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'mmHg'	System	17 Aug 2020 16:59:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 06:02:48

US3752088

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 06:02:48

US3752088

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:26
User closed query ' CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 19:44:14
Query ' CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:55:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:55:38
User opened query ' CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is required to be completed using the PE form located in the screening folder. Please ensure physical exam is entered in screening folder or confirm that physical exam was not completed. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 17:44:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:59:57

US3752088

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:26
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:55:38
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 17:44:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:44:25
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 18:31:13
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:27:25
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:59:57

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:35:04
User closed query 'Please consider removing other category if this falls under healthcare worker category.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 17:39:02
Query 'Please consider removing other category if this falls under healthcare worker category.' answered with 'entry error' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:21:05
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:14:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:14:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:14:12
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:13:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:13:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:12:58
User opened query 'Please consider removing other category if this falls under healthcare worker category.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:04:25
User closed query 'Please confirm if this falls under healthcare worker category.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:04:25
Query 'Please confirm if this falls under healthcare worker category.' answered with 'yes, Physician works in an office building with 20+ people' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 16:14:42
User opened query 'Please confirm if this falls under healthcare worker category.' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:43:22
DataPoint Un-verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:34
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:02:15
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:35:06
User closed query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	14 Sep 2020 17:13:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:13:23
User opened query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	14 Sep 2020 17:12:58
DataPoint Un-verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:35
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered 'Physician - insurance' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:02:15
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:42:25
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:01:38

US3752088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:04
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:02:37

US3752088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:04
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:34
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:02:37

US3752088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[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 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:04
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Aug 2020 17:02:37

US3752088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:04
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'VISIT1'	System	17 Aug 2020 17:02:37

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:37
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:49:21

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:35:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:27:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:27:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 14:49:21
User entered '104115' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:49:21

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:49:21

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

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 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:43:41
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:02:50

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

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 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:43:45
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:02:50

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:43
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:02:50

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:46
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:02:50

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:43:47
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:02:50

US3752088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:13

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:34:55
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 18:44:44
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:14:32

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User closed query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:06:42
Query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:51:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User opened query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:44:02
User entered '74.0' in	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User entered '230.1' lb	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User closed query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:06:42
Query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:51:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User opened query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:44:02
User entered '74.0' in	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User entered '230.1' lb	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User entered '09:00'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered '14 Aug 2020 09:00'	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User entered '98.3' F	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:51
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:04:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:04:51
User entered '54' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:04:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'bpm'	System	17 Aug 2020 17:04:51
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:04:51
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:04:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'breaths/min'	System	17 Aug 2020 17:04:51
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:04:51
User entered '126' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:04:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'mmHg'	System	17 Aug 2020 17:04:51
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:16
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:04:51
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:04:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'mmHg'	System	17 Aug 2020 17:04:51
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User closed query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:06:42
Query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:51:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User opened query 'Per CRF guidelines, If participant is screened, enrolled, randomized, and dose on the same day record height and weight on screening page. For Visit 1 Day 1 please consider marking height and weight as ND. ' (Site from CRA).	(b) (4), (b) (6)	12 Sep 2020 21:44:02
User entered '74.0' in	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:06:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:51:38
User entered '230.1' lb	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:27:51
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 17:04:23
User entered '10:35'	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered '14 Aug 2020 10:35'	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:45:14
User entered '98.1' F	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:05:35
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:05:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:05:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:05:35
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:05:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'bpm'	System	17 Aug 2020 17:05:35
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:05:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:05:35
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:05:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'breaths/min'	System	17 Aug 2020 17:05:35
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:05:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:05:35
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:05:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'mmHg'	System	17 Aug 2020 17:05:35
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:14
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:05:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:05:35
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:05:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:04:23
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'mmHg'	System	17 Aug 2020 17:05:35
User entered empty.	System	17 Aug 2020 17:04:23

US3752088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:25
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 20:45:07
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'PER CDM: DATA ENTRY CORRECTED.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 16:37:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 16:37:21

US3752088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 16:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:05:48

US3752088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 16:37:21
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:05:48

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered '10:05'	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered '14 Aug 2020 10:05'	System	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:45:43
User entered 'ONCE'	System	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:28
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 15:36:47

US3752088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:33
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:06:12

US3752088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:33
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:59
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:06:12

US3752088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:33
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:45:59
User entered '09:37'	(b) (4), (b) (6)	17 Aug 2020 17:06:12

US3752088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:33
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered '14 Aug 2020 09:37'	System	17 Aug 2020 17:06:12

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:46:09
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	17 Aug 2020 17:06:31
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Aug 2020 17:06:31
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:06:31
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	17 Aug 2020 17:06:24
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:46:09
User entered '09:35'	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered '14 Aug 2020 09:35'	System	17 Aug 2020 17:06:31
User entered empty.	System	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:46:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	12 Sep 2020 21:46:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered empty.	System	17 Aug 2020 17:06:24

US3752088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:43
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 21:46:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:06:37

US3752088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:43
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'l'	System	17 Aug 2020 17:06:37

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:37:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1fd546-6b2c-44b4-bc14-70bbbb2638b3' User entered 'Yes (Y)'	System	14 Aug 2020 15:38:10
	System	14 Aug 2020 15:38:10

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:37:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1fd546-6b2c-44b4-bc14-70bbbb2638b3' User entered '98.1'	System	14 Aug 2020 15:38:10
	System	14 Aug 2020 15:38:10

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1fd546-6b2c-44b4-bc14-70bbbb2638b3' User entered 'No (N)'	System	14 Aug 2020 15:38:10
	System	14 Aug 2020 15:38:10

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:08', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1fd546-6b2c-44b4-bc14-70bbbb2638b3' User entered '14 Aug 2020 10:38'	System	14 Aug 2020 15:38:10
	System	14 Aug 2020 15:38:10

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 12:55'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:38:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '26056e7e-a35c-41f4-a67a-6b8069810ba6' User entered 'Yes (Y)'	System	14 Aug 2020 22:38:55
	System	14 Aug 2020 22:38:55

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:38:40', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '26056e7e-a35c-41f4-a67a-6b8069810ba6' User entered '98.6'	System	14 Aug 2020 22:38:55
	System	14 Aug 2020 22:38:55

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:38:43', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '26056e7e-a35c-41f4-a67a-6b8069810ba6'	System	14 Aug 2020 22:38:55
User entered 'No (N)'	System	14 Aug 2020 22:38:55

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:38:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '26056e7e-a35c-41f4-a67a-6b8069810ba6'	System	14 Aug 2020 22:38:55
User entered '14 Aug 2020 17:38'	System	14 Aug 2020 22:38:55

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 13:50'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 2'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:34:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '928f5770-ffd6-46d4-b314-460b07e2e5ab' User entered 'Yes (Y)'	System	15 Aug 2020 22:35:15
	System	15 Aug 2020 22:35:15

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '928f5770-ffd6-46d4-b314-460b07e2e5ab' User entered '98.0'	System	15 Aug 2020 22:35:15
	System	15 Aug 2020 22:35:15

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '928f5770-ffd6-46d4-b314-460b07e2e5ab' User entered 'No (N)'	System	15 Aug 2020 22:35:15
	System	15 Aug 2020 22:35:15

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '928f5770-ffd6-46d4-b314-460b07e2e5ab' User entered '15 Aug 2020 17:35'	System	15 Aug 2020 22:35:15
	System	15 Aug 2020 22:35:15

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 3'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e683700b-d5b4-452e-95f6-7e723b027e86' User entered 'Yes (Y)'	System	16 Aug 2020 23:13:24
	System	16 Aug 2020 23:13:24

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:06', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e683700b-d5b4-452e-95f6-7e723b027e86' User entered '97.9'	System	16 Aug 2020 23:13:24
	System	16 Aug 2020 23:13:24

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:14', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e683700b-d5b4-452e-95f6-7e723b027e86'	System	16 Aug 2020 23:13:24
User entered 'No (N)'	System	16 Aug 2020 23:13:24

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:18', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e683700b-d5b4-452e-95f6-7e723b027e86' User entered '16 Aug 2020 18:13'	System	16 Aug 2020 23:13:24
	System	16 Aug 2020 23:13:24

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 4'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '4714dec1-f1c5-4e31-a2b2-49f31c836578' User entered 'Yes (Y)'	System	17 Aug 2020 23:06:36
	System	17 Aug 2020 23:06:36

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:27', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '4714dec1-f1c5-4e31-a2b2-49f31c836578' User entered '98.2'	System	17 Aug 2020 23:06:36
	System	17 Aug 2020 23:06:36

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '4714dec1-f1c5-4e31-a2b2-49f31c836578'	System	17 Aug 2020 23:06:36
User entered 'No (N)'	System	17 Aug 2020 23:06:36

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '4714dec1-f1c5-4e31-a2b2-49f31c836578' User entered '17 Aug 2020 18:06'	System	17 Aug 2020 23:06:36
	System	17 Aug 2020 23:06:36

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 5'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:03', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '83208230-29d2-463f-b1f8-267e0cade319'	System	19 Aug 2020 05:36:23
User entered 'Yes (Y)'	System	19 Aug 2020 05:36:23

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:11', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '83208230-29d2-463f-b1f8-267e0cade319' User entered '97.9'	System	19 Aug 2020 05:36:23
	System	19 Aug 2020 05:36:23

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '83208230-29d2-463f-b1f8-267e0cade319'	System	19 Aug 2020 05:36:23
User entered 'No (N)'	System	19 Aug 2020 05:36:23

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:20', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '83208230-29d2-463f-b1f8-267e0cade319'	System	19 Aug 2020 05:36:23
User entered '19 Aug 2020 00:36'	System	19 Aug 2020 05:36:23

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 6'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:58:50', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eeb6f09d-4377-4fb3-a38c-bd0e9b5c99f0' User entered 'Yes (Y)'	System	19 Aug 2020 23:59:04
	System	19 Aug 2020 23:59:04

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:58:55', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eeb6f09d-4377-4fb3-a38c-bd0e9b5c99f0' User entered '96.7'	System	19 Aug 2020 23:59:04
	System	19 Aug 2020 23:59:04

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:58:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eeb6f09d-4377-4fb3-a38c-bd0e9b5c99f0'	System	19 Aug 2020 23:59:04
User entered 'No (N)'	System	19 Aug 2020 23:59:04

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:01', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eeb6f09d-4377-4fb3-a38c-bd0e9b5c99f0'	System	19 Aug 2020 23:59:04
User entered '19 Aug 2020 18:59'	System	19 Aug 2020 23:59:04

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 7'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '164822fc-587c-4883-ac32-d64271d031a2' User entered 'Yes (Y)'	System	20 Aug 2020 22:49:25
	System	20 Aug 2020 22:49:25

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:18', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '164822fc-587c-4883-ac32-d64271d031a2' User entered '98.2'	System	20 Aug 2020 22:49:25
	System	20 Aug 2020 22:49:25

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '164822fc-587c-4883-ac32-d64271d031a2'	System	20 Aug 2020 22:49:25
User entered 'No (N)'	System	20 Aug 2020 22:49:25

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '164822fc-587c-4883-ac32-d64271d031a2' User entered '20 Aug 2020 17:49'	System	20 Aug 2020 22:49:25
	System	20 Aug 2020 22:49:25

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:16', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8df4b2ec-f57d-44ac-8f9b-7c5adfc0cae2'	System	14 Aug 2020 15:38:30
User entered 'None (1)'	System	14 Aug 2020 15:38:30

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8df4b2ec-f57d-44ac-8f9b-7c5adfc0cae2'	System	14 Aug 2020 15:38:30
User entered 'No (N)'	System	14 Aug 2020 15:38:30

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:22', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8df4b2ec-f57d-44ac-8f9b-7c5adfc0cae2'	System	14 Aug 2020 15:38:30
User entered 'No (N)'	System	14 Aug 2020 15:38:30

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8df4b2ec-f57d-44ac-8f9b-7c5adfc0cae2'	System	14 Aug 2020 15:38:30
User entered 'None (1)'	System	14 Aug 2020 15:38:30

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8df4b2ec-f57d-44ac-8f9b-7c5adfc0cae2'	System	14 Aug 2020 15:38:30
User entered '14 Aug 2020 10:38'	System	14 Aug 2020 15:38:30

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 12:55'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:03', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0453bf15-effa-4423-9118-86571f6f439f' User entered 'None (1)'	System	14 Aug 2020 22:39:23
	System	14 Aug 2020 22:39:23

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0453bf15-effa-4423-9118-86571f6f439f' User entered 'No (N)'	System	14 Aug 2020 22:39:23
	System	14 Aug 2020 22:39:23

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:13', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0453bf15-effa-4423-9118-86571f6f439f' User entered 'No (N)'	System	14 Aug 2020 22:39:23
	System	14 Aug 2020 22:39:23

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0453bf15-ffa-4423-9118-86571f6f439f' User entered 'None (1)'	System	14 Aug 2020 22:39:23
	System	14 Aug 2020 22:39:23

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0453bf15-ffa-4423-9118-86571f6f439f' User entered '14 Aug 2020 17:39'	System	14 Aug 2020 22:39:23
	System	14 Aug 2020 22:39:23

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 13:50'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 2'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e94777c3-68b4-4f34-b37d-cbb329953c4a' User entered 'None (1)'	System	15 Aug 2020 22:35:31
	System	15 Aug 2020 22:35:31

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e94777c3-68b4-4f34-b37d-cbb329953c4a' User entered 'No (N)'	System	15 Aug 2020 22:35:31
	System	15 Aug 2020 22:35:31

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e94777c3-68b4-4f34-b37d-cbb329953c4a' User entered 'No (N)'	System	15 Aug 2020 22:35:31
	System	15 Aug 2020 22:35:31

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e94777c3-68b4-4f34-b37d-cbb329953c4a' User entered 'None (1)'	System	15 Aug 2020 22:35:31
	System	15 Aug 2020 22:35:31

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e94777c3-68b4-4f34-b37d-cbb329953c4a' User entered '15 Aug 2020 17:35'	System	15 Aug 2020 22:35:31
	System	15 Aug 2020 22:35:31

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 3'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:22', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b05bd3d2-b50b-421e-8076-a1dd82892c32'	System	16 Aug 2020 23:14:04
User entered 'None (1)'	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b05bd3d2-b50b-421e-8076-a1dd82892c32'	System	16 Aug 2020 23:14:04
User entered 'No (N)'	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b05bd3d2-b50b-421e-8076-a1dd82892c32'	System	16 Aug 2020 23:14:04
User entered 'No (N)'	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b05bd3d2-b50b-421e-8076-a1dd82892c32'	System	16 Aug 2020 23:14:04
User entered 'None (1)'	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b05bd3d2-b50b-421e-8076-a1dd82892c32'	System	16 Aug 2020 23:14:04
User entered '16 Aug 2020 18:13'	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 4'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b827cd71-ace2-4d11-8188-b5b9df73a686' User entered 'None (1)'	System	17 Aug 2020 23:07:00
	System	17 Aug 2020 23:07:00

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b827cd71-ace2-4d11-8188-b5b9df73a686' User entered 'No (N)'	System	17 Aug 2020 23:07:00
	System	17 Aug 2020 23:07:00

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:48', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b827cd71-ace2-4d11-8188-b5b9df73a686' User entered 'No (N)'	System	17 Aug 2020 23:07:00
	System	17 Aug 2020 23:07:00

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b827cd71-ace2-4d11-8188-b5b9df73a686'	System	17 Aug 2020 23:07:00
User entered 'None (1)'	System	17 Aug 2020 23:07:00

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:55', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b827cd71-ace2-4d11-8188-b5b9df73a686' User entered '17 Aug 2020 18:06'	System	17 Aug 2020 23:07:00
	System	17 Aug 2020 23:07:00

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 5'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f25cca4f-fe14-424b-a9bb-6bdcf05afbe1' User entered 'None (1)'	System	19 Aug 2020 05:36:38
	System	19 Aug 2020 05:36:38

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f25cca4f-fe14-424b-a9bb-6bdcf05afbe1' User entered 'No (N)'	System	19 Aug 2020 05:36:38
	System	19 Aug 2020 05:36:38

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:32', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f25cca4f-fe14-424b-a9bb-6bdcf05afbe1'	System	19 Aug 2020 05:36:38
User entered 'No (N)'	System	19 Aug 2020 05:36:38

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:34', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f25cca4f-fe14-424b-a9bb-6bdcf05afbe1' User entered 'None (1)'	System	19 Aug 2020 05:36:38
	System	19 Aug 2020 05:36:38

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f25cca4f-fe14-424b-a9bb-6bdcf05afbe1'	System	19 Aug 2020 05:36:38
User entered '19 Aug 2020 00:36'	System	19 Aug 2020 05:36:38

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 6'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f6339f2b-c5d5-44a0-a1e1-a05db9d4755a' User entered 'None (1)'	System	19 Aug 2020 23:59:32
	System	19 Aug 2020 23:59:32

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f6339f2b-c5d5-44a0-a1e1-a05db9d4755a' User entered 'No (N)'	System	19 Aug 2020 23:59:32
	System	19 Aug 2020 23:59:32

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:23', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f6339f2b-c5d5-44a0-a1e1-a05db9d4755a' User entered 'No (N)'	System	19 Aug 2020 23:59:32
	System	19 Aug 2020 23:59:32

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f6339f2b-c5d5-44a0-a1e1-a05db9d4755a' User entered 'None (1)'	System	19 Aug 2020 23:59:32
	System	19 Aug 2020 23:59:32

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f6339f2b-c5d5-44a0-a1e1-a05db9d4755a' User entered '19 Aug 2020 18:59'	System	19 Aug 2020 23:59:32
	System	19 Aug 2020 23:59:32

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 7'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:27', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09bd0789-a02c-4879-a95b-8766e6a19130'	System	20 Aug 2020 22:49:42
User entered 'None (1)'	System	20 Aug 2020 22:49:42

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09bd0789-a02c-4879-a95b-8766e6a19130'	System	20 Aug 2020 22:49:42
User entered 'No (N)'	System	20 Aug 2020 22:49:42

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09bd0789-a02c-4879-a95b-8766e6a19130' User entered 'No (N)'	System	20 Aug 2020 22:49:42
	System	20 Aug 2020 22:49:42

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:36', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09bd0789-a02c-4879-a95b-8766e6a19130'	System	20 Aug 2020 22:49:42
User entered 'None (1)'	System	20 Aug 2020 22:49:42

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09bd0789-a02c-4879-a95b-8766e6a19130' User entered '20 Aug 2020 17:49'	System	20 Aug 2020 22:49:42
	System	20 Aug 2020 22:49:42

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:36', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:40', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526' User entered 'None (0)'	System	14 Aug 2020 15:38:59
	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526'	System	14 Aug 2020 15:38:59
User entered 'No (N)'	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T10:38:56', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '72adc5ea-c693-4a0d-a56d-31b0cf1aa526'	System	14 Aug 2020 15:38:59
User entered '14 Aug 2020 10:38'	System	14 Aug 2020 15:38:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 12:55'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:26', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:31', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'None (0)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:41', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered 'No (N)'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-14T17:39:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eb8f1748-570c-450c-a9bb-700913abbb79' User entered '14 Aug 2020 17:39'	System	14 Aug 2020 22:39:45
	System	14 Aug 2020 22:39:45

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Aug 2020 13:50'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 2'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:34', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:36', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:41', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'None (0)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:55', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered 'No (N)'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-15T17:35:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f584486a-ae8a-438e-9c61-d0ddb7320a3e' User entered '15 Aug 2020 17:35'	System	15 Aug 2020 22:35:59
	System	15 Aug 2020 22:35:59

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 3'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:40', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:47', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'None (0)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:13:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered 'No (N)'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-16T18:14:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'adcc973f-c149-4ae8-90b1-265ffdb415be' User entered '16 Aug 2020 18:14'	System	16 Aug 2020 23:14:04
	System	16 Aug 2020 23:14:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 4'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:06:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:01', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:03', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:08', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'None (0)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered 'No (N)'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-17T18:07:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2a556eb-851c-4286-9196-d5929e18b89e' User entered '17 Aug 2020 18:07'	System	17 Aug 2020 23:07:27
	System	17 Aug 2020 23:07:27

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 5'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:41', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:43', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'None (0)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:36:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered 'No (N)'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T00:37:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b7f677f2-2fa2-4304-b974-439787df5b5a' User entered '19 Aug 2020 00:37'	System	19 Aug 2020 05:37:04
	System	19 Aug 2020 05:37:04

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 6'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92' User entered 'None (0)'	System	20 Aug 2020 00:00:39
	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:50', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92' User entered 'None (0)'	System	20 Aug 2020 00:00:39
	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92' User entered 'None (0)'	System	20 Aug 2020 00:00:39
	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T18:59:55', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92' User entered 'None (0)'	System	20 Aug 2020 00:00:39
	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T19:00:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92' User entered 'None (0)'	System	20 Aug 2020 00:00:39
	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T19:00:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92'	System	20 Aug 2020 00:00:39
User entered 'None (0)'	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T19:00:13', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92'	System	20 Aug 2020 00:00:39
User entered 'No (N)'	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-19T19:00:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '61d66a99-e61c-4cae-b4bf-33cb851c9c92'	System	20 Aug 2020 00:00:39
User entered '19 Aug 2020 19:00'	System	20 Aug 2020 00:00:39

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 7'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:46', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:48', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:50', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'None (0)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:49:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered 'No (N)'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-08-20T17:50:01', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6675f05a-b758-4e4f-996e-0311718a5ce6' User entered '20 Aug 2020 17:50'	System	20 Aug 2020 22:50:05
	System	20 Aug 2020 22:50:05

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:36:47

US3752088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 15:32:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Aug 2020 01:30:58

US3752088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:32:34
User entered '21 Aug 2020'	(b) (4), (b) (6)	23 Aug 2020 01:30:58

US3752088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 15:32:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Aug 2020 01:30:58

US3752088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:49
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 15:32:34
User entered empty.	(b) (4), (b) (6)	23 Aug 2020 01:30:58

US3752088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:32:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:26:48

US3752088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:29:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'l'	System	11 Sep 2020 16:26:48

US3752088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:13:31
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:20:43

US3752088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:13:31
User entered '28 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:20:43

US3752088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:13:31
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:20:43

US3752088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:13:31
User entered empty.	Amanda Horn (b) (4)	22 Oct 2020 19:20:43
	(b) (4)	

US3752088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:13:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:26:56

US3752088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 09:30:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:08:56
User entered 'l'	System	11 Sep 2020 16:26:56

US3752088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:54
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:10:39

US3752088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:54
User entered '4 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:10:39

US3752088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:54
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:10:39

US3752088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:02:54
User entered empty.	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:10:39

US3752088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:03:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:27:12

US3752088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '1'	System	11 Sep 2020 16:27:12

US3752088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:33:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:27:25

US3752088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:33:50
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:27:25

US3752088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[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 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:33:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 16:27:25

US3752088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'VISIT2'	System	11 Sep 2020 16:27:25

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:28:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:23:04
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered '10:36'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '11 Sep 2020 10:36'	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered '97.9' F	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:27:54
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:27:54
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'bpm'	System	14 Sep 2020 21:27:54
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:27:54
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'breaths/min'	System	14 Sep 2020 21:27:54
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:27:54
User entered '114' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	14 Sep 2020 21:27:54
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:27:54
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:27:54
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	14 Sep 2020 21:27:54
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '11:55' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '11 Sep 2020 11:55'	System	14 Sep 2020 21:28:42
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'bpm'	System	14 Sep 2020 21:28:42
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'breaths/min'	System	14 Sep 2020 21:28:42
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	14 Sep 2020 21:28:42
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:01
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:28:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 21:28:42
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 21:28:42
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:27:29
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	14 Sep 2020 21:28:42
User entered empty.	System	14 Sep 2020 21:27:29

US3752088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:29:10

US3752088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:08
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:29:10

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered '11:23'	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '11 Sep 2020 11:23'	System	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 15:34:02
User entered 'ONCE'	System	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 16:27:51

US3752088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:29:24

US3752088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:19
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:29:24

US3752088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:19
User entered '10:50'	(b) (4), (b) (6)	14 Sep 2020 21:29:24

US3752088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '11 Sep 2020 10:50'	System	14 Sep 2020 21:29:24

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:25:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:25
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:25
User entered '10:48'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '11 Sep 2020 10:48'	System	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:25
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:25
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered empty.	System	14 Sep 2020 21:29:39

US3752088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:36:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:29:46

US3752088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'I'	System	14 Sep 2020 21:29:46

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:11', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '64fe6cee-3824-4399-aff2-d9a4212ed9c4' User entered 'Yes (Y)'	System	11 Sep 2020 16:44:26
	System	11 Sep 2020 16:44:26

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:18', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '64fe6cee-3824-4399-aff2-d9a4212ed9c4' User entered '98.0'	System	11 Sep 2020 16:44:26
	System	11 Sep 2020 16:44:26

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '64fe6cee-3824-4399-aff2-d9a4212ed9c4'	System	11 Sep 2020 16:44:26
User entered 'No (N)'	System	11 Sep 2020 16:44:26

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '64fe6cee-3824-4399-aff2-d9a4212ed9c4'	System	11 Sep 2020 16:44:26
User entered '11 Sep 2020 11:44'	System	11 Sep 2020 16:44:26

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 11:43'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 14:13'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:45:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b18dc223-6753-49bd-b28b-18f0c88ace20' User entered 'Yes (Y)'	System	12 Sep 2020 11:46:14
	System	12 Sep 2020 11:46:14

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:06', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b18dc223-6753-49bd-b28b-18f0c88ace20' User entered '96.6'	System	12 Sep 2020 11:46:14
	System	12 Sep 2020 11:46:14

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:09', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b18dc223-6753-49bd-b28b-18f0c88ace20' User entered 'No (N)'	System	12 Sep 2020 11:46:14
	System	12 Sep 2020 11:46:14

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:12', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b18dc223-6753-49bd-b28b-18f0c88ace20' User entered '12 Sep 2020 06:46'	System	12 Sep 2020 11:46:14
	System	12 Sep 2020 11:46:14

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 15:08'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 2'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:01:50', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6a462a9a-3e8e-49f2-bf40-6022c5b7ed74' User entered 'Yes (Y)'	System	13 Sep 2020 11:02:11
	System	13 Sep 2020 11:02:11

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:01:56', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6a462a9a-3e8e-49f2-bf40-6022c5b7ed74' User entered '97.5'	System	13 Sep 2020 11:02:11
	System	13 Sep 2020 11:02:11

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6a462a9a-3e8e-49f2-bf40-6022c5b7ed74' User entered 'No (N)'	System	13 Sep 2020 11:02:11
	System	13 Sep 2020 11:02:11

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:03', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '6a462a9a-3e8e-49f2-bf40-6022c5b7ed74'	System	13 Sep 2020 11:02:11
User entered '13 Sep 2020 06:02'	System	13 Sep 2020 11:02:11

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 3'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '924aeb7e-ed8e-4e7c-855c-8eee47eaba22'	System	13 Sep 2020 18:02:15
User entered 'Yes (Y)'	System	13 Sep 2020 18:02:15

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '924aeb7e-ed8e-4e7c-855c-8eee47eaba22' User entered '98.1'	System	13 Sep 2020 18:02:15
	System	13 Sep 2020 18:02:15

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '924aeb7e-ed8e-4e7c-855c-8eee47eaba22'	System	13 Sep 2020 18:02:15
User entered 'No (N)'	System	13 Sep 2020 18:02:15

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:12', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '924aeb7e-ed8e-4e7c-855c-8eee47eaba22'	System	13 Sep 2020 18:02:15
User entered '13 Sep 2020 13:02'	System	13 Sep 2020 18:02:15

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 4'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:01:32', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1ec96fec-3252-402d-88f0-89cd61976f48'	System	14 Sep 2020 17:03:03
User entered 'Yes (Y)'	System	14 Sep 2020 17:03:03

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:01:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1ec96fec-3252-402d-88f0-89cd61976f48' User entered '97.2'	System	14 Sep 2020 17:03:03
	System	14 Sep 2020 17:03:03

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:01:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1ec96fec-3252-402d-88f0-89cd61976f48'	System	14 Sep 2020 17:03:03
User entered 'No (N)'	System	14 Sep 2020 17:03:03

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:01:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1ec96fec-3252-402d-88f0-89cd61976f48'	System	14 Sep 2020 17:03:03
User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:03:03

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 5'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:11:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f52c590d-9fd6-4636-8901-315755471018' User entered 'Yes (Y)'	System	15 Sep 2020 23:11:57
	System	15 Sep 2020 23:11:57

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:11:43', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f52c590d-9fd6-4636-8901-315755471018' User entered '97.3'	System	15 Sep 2020 23:11:57
	System	15 Sep 2020 23:11:57

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:11:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f52c590d-9fd6-4636-8901-315755471018'	System	15 Sep 2020 23:11:57
User entered 'No (N)'	System	15 Sep 2020 23:11:57

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:11:54', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'f52c590d-9fd6-4636-8901-315755471018' User entered '15 Sep 2020 18:11'	System	15 Sep 2020 23:11:57
	System	15 Sep 2020 23:11:57

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 6'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:00:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0f57750b-8c33-40b1-8c4f-6c7ca1001511' User entered 'Yes (Y)'	System	16 Sep 2020 17:01:22
	System	16 Sep 2020 17:01:22

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:00:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0f57750b-8c33-40b1-8c4f-6c7ca1001511' User entered '97.6'	System	16 Sep 2020 17:01:22
	System	16 Sep 2020 17:01:22

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:00:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0f57750b-8c33-40b1-8c4f-6c7ca1001511' User entered 'No (N)'	System	16 Sep 2020 17:01:22
	System	16 Sep 2020 17:01:22

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:00:54', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0f57750b-8c33-40b1-8c4f-6c7ca1001511' User entered '16 Sep 2020 12:00'	System	16 Sep 2020 17:01:22
	System	16 Sep 2020 17:01:22

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 7'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:16:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '03030063-2067-41cb-81fc-2418617a13d5'	System	17 Sep 2020 17:17:08
User entered 'Yes (Y)'	System	17 Sep 2020 17:17:08

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:16:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '03030063-2067-41cb-81fc-2418617a13d5' User entered '97.6'	System	17 Sep 2020 17:17:08
	System	17 Sep 2020 17:17:08

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:16:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '03030063-2067-41cb-81fc-2418617a13d5'	System	17 Sep 2020 17:17:08
User entered 'No (N)'	System	17 Sep 2020 17:17:08

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:01', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '03030063-2067-41cb-81fc-2418617a13d5'	System	17 Sep 2020 17:17:08
User entered '17 Sep 2020 12:17'	System	17 Sep 2020 17:17:08

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b5b42844-d57a-404c-bb75-14a1b19cde90'	System	11 Sep 2020 16:44:44
User entered 'None (1)'	System	11 Sep 2020 16:44:44

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b5b42844-d57a-404c-bb75-14a1b19cde90'	System	11 Sep 2020 16:44:44
User entered 'No (N)'	System	11 Sep 2020 16:44:44

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b5b42844-d57a-404c-bb75-14a1b19cde90'	System	11 Sep 2020 16:44:44
User entered 'No (N)'	System	11 Sep 2020 16:44:44

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b5b42844-d57a-404c-bb75-14a1b19cde90'	System	11 Sep 2020 16:44:44
User entered 'None (1)'	System	11 Sep 2020 16:44:44

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:41', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b5b42844-d57a-404c-bb75-14a1b19cde90'	System	11 Sep 2020 16:44:44
User entered '11 Sep 2020 11:44'	System	11 Sep 2020 16:44:44

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 11:43'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 14:13'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:18', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5064a159-9227-4e0a-9b3d-2a923060385c' User entered 'None (1)'	System	12 Sep 2020 11:46:31
	System	12 Sep 2020 11:46:31

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5064a159-9227-4e0a-9b3d-2a923060385c' User entered 'No (N)'	System	12 Sep 2020 11:46:31
	System	12 Sep 2020 11:46:31

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5064a159-9227-4e0a-9b3d-2a923060385c' User entered 'No (N)'	System	12 Sep 2020 11:46:31
	System	12 Sep 2020 11:46:31

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:27', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5064a159-9227-4e0a-9b3d-2a923060385c' User entered 'None (1)'	System	12 Sep 2020 11:46:31
	System	12 Sep 2020 11:46:31

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5064a159-9227-4e0a-9b3d-2a923060385c' User entered '12 Sep 2020 06:46'	System	12 Sep 2020 11:46:31
	System	12 Sep 2020 11:46:31

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 15:08'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 2'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '28720527-605f-4a18-8eeb-34e92cad4ac4'	System	13 Sep 2020 11:02:54
User entered 'None (1)'	System	13 Sep 2020 11:02:54

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:16', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '28720527-605f-4a18-8eeb-34e92cad4ac4' User entered 'No (N)'	System	13 Sep 2020 11:02:54
	System	13 Sep 2020 11:02:54

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '28720527-605f-4a18-8eeb-34e92cad4ac4' User entered 'No (N)'	System	13 Sep 2020 11:02:54
	System	13 Sep 2020 11:02:54

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '28720527-605f-4a18-8eeb-34e92cad4ac4'	System	13 Sep 2020 11:02:54
User entered 'None (1)'	System	13 Sep 2020 11:02:54

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:02:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '28720527-605f-4a18-8eeb-34e92cad4ac4'	System	13 Sep 2020 11:02:54
User entered '13 Sep 2020 06:02'	System	13 Sep 2020 11:02:54

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 3'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:16', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09f9b02b-90f3-4ca0-8dc3-943899516657'	System	13 Sep 2020 18:02:30
User entered 'None (1)'	System	13 Sep 2020 18:02:30

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09f9b02b-90f3-4ca0-8dc3-943899516657'	System	13 Sep 2020 18:02:30
User entered 'No (N)'	System	13 Sep 2020 18:02:30

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09f9b02b-90f3-4ca0-8dc3-943899516657' User entered 'No (N)'	System	13 Sep 2020 18:02:30
	System	13 Sep 2020 18:02:30

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09f9b02b-90f3-4ca0-8dc3-943899516657'	System	13 Sep 2020 18:02:30
User entered 'None (1)'	System	13 Sep 2020 18:02:30

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:26', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '09f9b02b-90f3-4ca0-8dc3-943899516657'	System	13 Sep 2020 18:02:30
User entered '13 Sep 2020 13:02'	System	13 Sep 2020 18:02:30

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 4'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:02:01', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eff0333c-4c17-4723-a94b-609e88b3bce5'	System	14 Sep 2020 17:04:42
User entered 'None (1)'	System	14 Sep 2020 17:04:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:02:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eff0333c-4c17-4723-a94b-609e88b3bce5'	System	14 Sep 2020 17:04:42
User entered 'No (N)'	System	14 Sep 2020 17:04:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:02:20', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eff0333c-4c17-4723-a94b-609e88b3bce5' User entered 'No (N)'	System	14 Sep 2020 17:04:42
	System	14 Sep 2020 17:04:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:02:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eff0333c-4c17-4723-a94b-609e88b3bce5'	System	14 Sep 2020 17:04:42
User entered 'None (1)'	System	14 Sep 2020 17:04:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:14', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'eff0333c-4c17-4723-a94b-609e88b3bce5'	System	14 Sep 2020 17:04:42
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 5'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8c5e477a-0e76-4df5-afa3-200b0a50ea80'	System	15 Sep 2020 23:12:47
User entered 'None (1)'	System	15 Sep 2020 23:12:47

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8c5e477a-0e76-4df5-afa3-200b0a50ea80' User entered 'No (N)'	System	15 Sep 2020 23:12:47
	System	15 Sep 2020 23:12:47

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:34', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8c5e477a-0e76-4df5-afa3-200b0a50ea80' User entered 'No (N)'	System	15 Sep 2020 23:12:47
	System	15 Sep 2020 23:12:47

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:40', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8c5e477a-0e76-4df5-afa3-200b0a50ea80'	System	15 Sep 2020 23:12:47
User entered 'None (1)'	System	15 Sep 2020 23:12:47

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8c5e477a-0e76-4df5-afa3-200b0a50ea80' User entered '15 Sep 2020 18:12'	System	15 Sep 2020 23:12:47
	System	15 Sep 2020 23:12:47

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 6'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:00:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ac01d04e-b92c-48bb-95ec-aed50a02bf7e' User entered 'None (1)'	System	16 Sep 2020 17:01:42
	System	16 Sep 2020 17:01:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ac01d04e-b92c-48bb-95ec-aed50a02bf7e' User entered 'No (N)'	System	16 Sep 2020 17:01:42
	System	16 Sep 2020 17:01:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ac01d04e-b92c-48bb-95ec-aed50a02bf7e' User entered 'No (N)'	System	16 Sep 2020 17:01:42
	System	16 Sep 2020 17:01:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ac01d04e-b92c-48bb-95ec-aed50a02bf7e' User entered 'None (1)'	System	16 Sep 2020 17:01:42
	System	16 Sep 2020 17:01:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ac01d04e-b92c-48bb-95ec-aed50a02bf7e' User entered '16 Sep 2020 12:01'	System	16 Sep 2020 17:01:42
	System	16 Sep 2020 17:01:42

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 7'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:04', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d4d124b-616d-44a8-9198-0108d227f968'	System	17 Sep 2020 17:17:16
User entered 'None (1)'	System	17 Sep 2020 17:17:16

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d4d124b-616d-44a8-9198-0108d227f968' User entered 'No (N)'	System	17 Sep 2020 17:17:16
	System	17 Sep 2020 17:17:16

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:09', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d4d124b-616d-44a8-9198-0108d227f968' User entered 'No (N)'	System	17 Sep 2020 17:17:16
	System	17 Sep 2020 17:17:16

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:11', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d4d124b-616d-44a8-9198-0108d227f968'	System	17 Sep 2020 17:17:16
User entered 'None (1)'	System	17 Sep 2020 17:17:16

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:13', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d4d124b-616d-44a8-9198-0108d227f968' User entered '17 Sep 2020 12:17'	System	17 Sep 2020 17:17:16
	System	17 Sep 2020 17:17:16

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:44:47', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:22', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:26', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:31', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'None (0)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4' User entered 'No (N)'	System	11 Sep 2020 16:45:49
	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-11T11:45:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c26c4b52-429c-4ff9-bdc9-b4322d65d1b4'	System	11 Sep 2020 16:45:49
User entered '11 Sep 2020 11:45'	System	11 Sep 2020 16:45:49

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 11:43'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 14:13'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:34', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:36', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:41', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:43', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'None (0)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered 'No (N)'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-12T06:46:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '516239db-c3d0-457e-8858-2faf51a95488' User entered '12 Sep 2020 06:46'	System	12 Sep 2020 11:46:58
	System	12 Sep 2020 11:46:58

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '11 Sep 2020 15:08'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 2'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:03:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:03:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:08', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'None (0)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered 'No (N)'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T06:04:23', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '39c6937b-a543-4b31-a4ed-78781c1a8a15' User entered '13 Sep 2020 06:04'	System	13 Sep 2020 11:04:26
	System	13 Sep 2020 11:04:26

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 3'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:32', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:34', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'None (0)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:42', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered 'No (N)'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-13T13:02:44', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7bd0c2a7-051b-42d5-a23f-7a1c453de6fa' User entered '13 Sep 2020 13:02'	System	13 Sep 2020 18:02:46
	System	13 Sep 2020 18:02:46

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 4'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:17', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:23', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:27', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'None (0)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:33', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered 'No (N)'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-14T12:03:35', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a8403895-1cc3-48f4-89c9-cee5838f85d3' User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:53
	System	14 Sep 2020 17:04:53

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 5'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:46', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:12:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:13:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:13:03', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'None (0)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:13:09', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered 'No (N)'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-15T18:13:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '0617e098-75e0-4a60-9d08-3d3ac31f527c' User entered '15 Sep 2020 18:13'	System	15 Sep 2020 23:13:17
	System	15 Sep 2020 23:13:17

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 6'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:10', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:13', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:17', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:18', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:20', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'None (0)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:23', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered 'No (N)'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-16T12:01:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'e873a57b-7f87-40d7-b163-f495c72c0ba8' User entered '16 Sep 2020 12:01'	System	16 Sep 2020 17:02:16
	System	16 Sep 2020 17:02:16

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	11 Sep 2020 16:27:51
User entered 'Day 7'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:17', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:19', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:23', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:26', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'None (0)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered 'No (N)'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-09-17T12:17:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'da4b901a-3a86-401d-b36e-ad73da3e8308' User entered '17 Sep 2020 12:17'	System	17 Sep 2020 17:17:33
	System	17 Sep 2020 17:17:33

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:27:51

US3752088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:27:51

US3752088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:34:07
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 21:03:34

US3752088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:34:07
User entered '18 Sep 2020'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 21:03:34

US3752088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:34:07
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 21:03:34

US3752088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:34:07
User entered empty.	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 21:03:34

US3752088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:35:44
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 21:03:39

US3752088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'I'	System	21 Sep 2020 21:03:39

US3752088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:45:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:52:43

US3752088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:45:58
User entered '25 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 14:52:43

US3752088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:45:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 14:52:43

US3752088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:52:43

US3752088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:46:04
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:08

US3752088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'I'	System	07 Oct 2020 22:34:08

US3752088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:55:14
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:46

US3752088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:55:14
User entered '2 Oct 2020'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:46

US3752088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:55:14
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:46

US3752088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:55:14
User entered empty.	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:46

US3752088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:55:23
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:34:49

US3752088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'I'	System	07 Oct 2020 22:34:49

US3752088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:57:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:45:11

US3752088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:57:49
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:45:11

US3752088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[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 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:57:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 18:45:11

US3752088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'VISIT3'	System	16 Oct 2020 18:45:11

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '07:35'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '16 Oct 2020 07:35'	System	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '98.1' F	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '63'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'bpm'	System	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '17'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'breaths/min'	System	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '126'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:58:33
User entered '84'	(b) (4), (b) (6)	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'mmHg'	System	16 Oct 2020 18:45:40

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41

US3752088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41

US3752088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:59:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:45:51

US3752088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 17:59:44
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:45:51

US3752088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:01:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:46:18

US3752088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:01:29
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:46:18

US3752088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:01:29
User entered '07:41'	(b) (4), (b) (6)	16 Oct 2020 18:46:18

US3752088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '16 Oct 2020 07:41'	System	16 Oct 2020 18:46:18

US3752088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:01:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:46:23

US3752088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered '1'	System	16 Oct 2020 18:46:23

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 64'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-14T06:49:14', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '20f421ef-15a9-4e99-b327-1a8c13614549'	System	14 Oct 2020 11:49:27
User entered 'No (N)'	System	14 Oct 2020 11:49:27

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-14T06:49:20', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '20f421ef-15a9-4e99-b327-1a8c13614549'	System	14 Oct 2020 11:49:27
User entered 'No (N)'	System	14 Oct 2020 11:49:27

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-14T06:49:24', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '20f421ef-15a9-4e99-b327-1a8c13614549' User entered '14 Oct 2020 06:49:24'	System	14 Oct 2020 11:49:27
	System	14 Oct 2020 11:49:27

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 71'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-21T18:49:04', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '883a89a4-5e8c-433e-b271-e2aeb83f1ff7'	System	21 Oct 2020 23:49:15
User entered 'No (N)'	System	21 Oct 2020 23:49:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-21T18:49:08', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '883a89a4-5e8c-433e-b271-e2aeb83f1ff7'	System	21 Oct 2020 23:49:15
User entered 'No (N)'	System	21 Oct 2020 23:49:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-21T18:49:11', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '883a89a4-5e8c-433e-b271-e2aeb83f1ff7' User entered '21 Oct 2020 18:49:11'	System	21 Oct 2020 23:49:15
	System	21 Oct 2020 23:49:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 78'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-28T04:34:06', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'd0951691-08b8-47da-8d03-32887081b15d' User entered 'No (N)'	System	28 Oct 2020 09:34:17
	System	28 Oct 2020 09:34:17

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-28T04:34:12', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'd0951691-08b8-47da-8d03-32887081b15d'	System	28 Oct 2020 09:34:17
User entered 'No (N)'	System	28 Oct 2020 09:34:17

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-10-28T04:34:15', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'd0951691-08b8-47da-8d03-32887081b15d' User entered '28 Oct 2020 04:34:15'	System	28 Oct 2020 09:34:17
	System	28 Oct 2020 09:34:17

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 92'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-11T05:28:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '930d10c1-0060-473b-9ba9-c4117c670b4f' User entered 'No (N)'	System	11 Nov 2020 11:28:18
	System	11 Nov 2020 11:28:18

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-11T05:28:12', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '930d10c1-0060-473b-9ba9-c4117c670b4f' User entered 'No (N)'	System	11 Nov 2020 11:28:18
	System	11 Nov 2020 11:28:18

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-11T05:28:16', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '930d10c1-0060-473b-9ba9-c4117c670b4f' User entered '11 Nov 2020 05:28:16'	System	11 Nov 2020 11:28:18
	System	11 Nov 2020 11:28:18

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered 'Day 99'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-18T03:33:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b47aa122-ee6f-46c6-8093-42cd1705a5e6'	System	18 Nov 2020 09:34:15
User entered 'No (N)'	System	18 Nov 2020 09:34:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-18T03:33:48', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b47aa122-ee6f-46c6-8093-42cd1705a5e6'	System	18 Nov 2020 09:34:15
User entered 'Yes (Y)'	System	18 Nov 2020 09:34:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Please contact your study clinic 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)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-18T03:33:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b47aa122-ee6f-46c6-8093-42cd1705a5e6'	System	18 Nov 2020 09:34:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 09:34:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-18T03:34:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'b47aa122-ee6f-46c6-8093-42cd1705a5e6' User entered '18 Nov 2020 03:34:05'	System	18 Nov 2020 09:34:15
	System	18 Nov 2020 09:34:15

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 15:36:47

US3752088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:23:10
Data entry locked.	System	14 Aug 2020 15:36:47
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 15:36:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-29T04:40:57', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8b8a360d-6fa9-4c57-9b35-4c7feb44fde3'	System	29 Nov 2020 10:41:09
User entered 'No (N)'	System	29 Nov 2020 10:41:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-29T04:41:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8b8a360d-6fa9-4c57-9b35-4c7feb44fde3'	System	29 Nov 2020 10:41:09
User entered 'No (N)'	System	29 Nov 2020 10:41:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-11-29T04:41:05', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8b8a360d-6fa9-4c57-9b35-4c7feb44fde3' User entered '29 Nov 2020 04:41:05'	System	29 Nov 2020 10:41:09
	System	29 Nov 2020 10:41:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-06T05:12:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'cd145422-2029-4ab1-ba50-9d641816dffc' User entered 'No (N)'	System	06 Dec 2020 11:12:56
	System	06 Dec 2020 11:12:56

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-06T05:12:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'cd145422-2029-4ab1-ba50-9d641816dffc' User entered 'No (N)'	System	06 Dec 2020 11:12:56

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-06T05:12:54', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'cd145422-2029-4ab1-ba50-9d641816dffc' User entered '06 Dec 2020 05:12:54'	System	06 Dec 2020 11:12:56
	System	06 Dec 2020 11:12:56

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (7331AC04-7901-45CD-9DFD-7555E152D915)', Time: '2020-12-13T00:06:47', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '86c781d7-a250-452d-b981-a22a03fa3401' User entered 'No (N)'	System	13 Dec 2020 06:06:58
	System	13 Dec 2020 06:06:58

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (7331AC04-7901-45CD-9DFD-7555E152D915)', Time: '2020-12-13T00:06:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '86c781d7-a250-452d-b981-a22a03fa3401' User entered 'No (N)'	System	13 Dec 2020 06:06:58

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7331AC04-7901-45CD-9DFD-7555E152D915)', Time: '2020-12-13T00:06:56', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '86c781d7-a250-452d-b981-a22a03fa3401' User entered '13 Dec 2020 00:06:56'	System	13 Dec 2020 06:06:58
	System	13 Dec 2020 06:06:58

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-20T02:41:54', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '45df6f85-b0db-4bbd-9926-f1a9f5e8b209'	System	20 Dec 2020 08:42:05
User entered 'No (N)'	System	20 Dec 2020 08:42:05

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-20T02:41:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '45df6f85-b0db-4bbd-9926-f1a9f5e8b209' User entered 'No (N)'	System	20 Dec 2020 08:42:05
	System	20 Dec 2020 08:42:05

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-20T02:42:04', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '45df6f85-b0db-4bbd-9926-f1a9f5e8b209' User entered '20 Dec 2020 02:42:04'	System	20 Dec 2020 08:42:05
	System	20 Dec 2020 08:42:05

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-27T03:33:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ae944239-2998-4c6c-9380-b6237cb3a058' User entered 'No (N)'	System	27 Dec 2020 09:34:06
	System	27 Dec 2020 09:34:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-27T03:33:58', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ae944239-2998-4c6c-9380-b6237cb3a058'	System	27 Dec 2020 09:34:06
User entered 'No (N)'	System	27 Dec 2020 09:34:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2020-12-27T03:34:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ae944239-2998-4c6c-9380-b6237cb3a058' User entered '27 Dec 2020 03:34:02'	System	27 Dec 2020 09:34:06
	System	27 Dec 2020 09:34:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-03T05:33:30', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '046117d8-5e79-41af-a56b-d92fdc45eee6'	System	03 Jan 2021 11:33:52
User entered 'No (N)'	System	03 Jan 2021 11:33:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-03T05:33:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '046117d8-5e79-41af-a56b-d92fdc45eee6'	System	03 Jan 2021 11:33:52
User entered 'No (N)'	System	03 Jan 2021 11:33:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-03T05:33:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '046117d8-5e79-41af-a56b-d92fdc45eee6'	System	03 Jan 2021 11:33:52
User entered '03 Jan 2021 05:33:49'	System	03 Jan 2021 11:33:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-10T05:12:45', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '2dea53c4-5726-4a57-9c3c-c631f978d16d' User entered 'No (N)'	System	10 Jan 2021 11:13:07
	System	10 Jan 2021 11:13:07

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-10T05:12:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '2dea53c4-5726-4a57-9c3c-c631f978d16d' User entered 'No (N)'	System	10 Jan 2021 11:13:07

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-10T05:13:04', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '2dea53c4-5726-4a57-9c3c-c631f978d16d' User entered '10 Jan 2021 05:13:04'	System	10 Jan 2021 11:13:07
	System	10 Jan 2021 11:13:07

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-17T07:06:39', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d6dea3d-e096-46ed-8bbb-4a480c13878f' User entered 'No (N)'	System	17 Jan 2021 13:07:25
	System	17 Jan 2021 13:07:25

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-17T07:06:59', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d6dea3d-e096-46ed-8bbb-4a480c13878f' User entered 'No (N)'	System	17 Jan 2021 13:07:25

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-17T07:07:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5d6dea3d-e096-46ed-8bbb-4a480c13878f' User entered '17 Jan 2021 07:07:21'	System	17 Jan 2021 13:07:25
	System	17 Jan 2021 13:07:25

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-24T12:55:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9fccf7ab-ec1e-47f3-96fd-0534d6044e32'	System	24 Jan 2021 18:55:54
User entered 'No (N)'	System	24 Jan 2021 18:55:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-24T12:55:46', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9fccf7ab-ec1e-47f3-96fd-0534d6044e32'	System	24 Jan 2021 18:55:54
User entered 'No (N)'	System	24 Jan 2021 18:55:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-24T12:55:52', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9fccf7ab-ec1e-47f3-96fd-0534d6044e32' User entered '24 Jan 2021 12:55:52'	System	24 Jan 2021 18:55:54
	System	24 Jan 2021 18:55:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-31T18:31:32', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '67380a7a-4242-46a1-bd3e-722a41aea22b' User entered 'No (N)'	System	01 Feb 2021 00:31:41
	System	01 Feb 2021 00:31:41

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-31T18:31:36', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '67380a7a-4242-46a1-bd3e-722a41aea22b' User entered 'No (N)'	System	01 Feb 2021 00:31:41
	System	01 Feb 2021 00:31:41

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-01-31T18:31:38', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '67380a7a-4242-46a1-bd3e-722a41aea22b' User entered '31 Jan 2021 18:31:38'	System	01 Feb 2021 00:31:41
	System	01 Feb 2021 00:31:41

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-07T05:24:17', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1c7d2b-d45f-4553-bb2a-e18d2f466cc8'	System	07 Feb 2021 11:24:26
User entered 'No (N)'	System	07 Feb 2021 11:24:26

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-07T05:24:21', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1c7d2b-d45f-4553-bb2a-e18d2f466cc8'	System	07 Feb 2021 11:24:26
User entered 'No (N)'	System	07 Feb 2021 11:24:26

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-07T05:24:25', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'aa1c7d2b-d45f-4553-bb2a-e18d2f466cc8' User entered '07 Feb 2021 05:24:25'	System	07 Feb 2021 11:24:26
	System	07 Feb 2021 11:24:26

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:07:51', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0' User entered 'Yes (Y)'	System	17 Feb 2021 02:17:23
	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:07:56', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0' User entered 'No (N)'	System	17 Feb 2021 02:17:23
	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you experienced any new COVID-19 disease symptoms 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:08:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0' User entered 'No (N)'	System	17 Feb 2021 02:17:23
	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had to contact a healthcare provider 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:08:07', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0' User entered 'Yes (Y)'	System	17 Feb 2021 02:17:23
	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:08:14', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0'	System	17 Feb 2021 02:17:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-16T20:08:28', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7c29e30c-b9c0-48f8-bab6-084a92b673b0' User entered '16 Feb 2021 20:08:28'	System	17 Feb 2021 02:17:23
	System	17 Feb 2021 02:17:23

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-23T04:28:49', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2edc815-68c3-4d5f-be54-5b591fd53a3f' User entered 'No (N)'	System	23 Feb 2021 10:28:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-23T04:28:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2edc815-68c3-4d5f-be54-5b591fd53a3f' User entered 'No (N)'	System	23 Feb 2021 10:28:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-23T04:28:56', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'a2edc815-68c3-4d5f-be54-5b591fd53a3f' User entered '23 Feb 2021 04:28:56'	System	23 Feb 2021 10:28:59
	System	23 Feb 2021 10:28:59

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-28T05:07:46', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7a107d65-cf43-4275-8671-27224edd102a' User entered 'No (N)'	System	28 Feb 2021 11:08:00
	System	28 Feb 2021 11:08:00

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-28T05:07:50', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7a107d65-cf43-4275-8671-27224edd102a' User entered 'No (N)'	System	28 Feb 2021 11:08:00
	System	28 Feb 2021 11:08:00

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-28T05:07:53', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7a107d65-cf43-4275-8671-27224edd102a' User entered '28 Feb 2021 05:07:53'	System	28 Feb 2021 11:08:00
	System	28 Feb 2021 11:08:00

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-11T18:59:29', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9f7cdb7-cc0e-4d70-91c6-7201a735c1f7'	System	12 Mar 2021 00:59:39
User entered 'No (N)'	System	12 Mar 2021 00:59:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-11T18:59:32', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9f7cdbe7-cc0e-4d70-91c6-7201a735c1f7'	System	12 Mar 2021 00:59:39
User entered 'No (N)'	System	12 Mar 2021 00:59:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-11T18:59:37', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '9f7cdbe7-cc0e-4d70-91c6-7201a735c1f7' User entered '11 Mar 2021 18:59:37'	System	12 Mar 2021 00:59:39
	System	12 Mar 2021 00:59:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-14T18:20:58-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'baf4bc3a-50ee-45e8-8745-d0bd74f02ede'	System	14 Mar 2021 23:21:09
User entered 'No (N)'	System	14 Mar 2021 23:21:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-14T18:21:02-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'baf4bc3a-50ee-45e8-8745-d0bd74f02ede'	System	14 Mar 2021 23:21:09
User entered 'No (N)'	System	14 Mar 2021 23:21:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-14T18:21:05-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'baf4bc3a-50ee-45e8-8745-d0bd74f02ede' User entered '14 Mar 2021 18:21:05'	System	14 Mar 2021 23:21:09
	System	14 Mar 2021 23:21:09

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-21T13:39:09-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '36972764-711f-4701-9cf9-d970305aee92'	System	21 Mar 2021 18:39:18
User entered 'No (N)'	System	21 Mar 2021 18:39:18

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-21T13:39:12-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '36972764-711f-4701-9cf9-d970305aee92'	System	21 Mar 2021 18:39:18
User entered 'No (N)'	System	21 Mar 2021 18:39:18

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-21T13:39:15-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '36972764-711f-4701-9cf9-d970305aee92'	System	21 Mar 2021 18:39:18
User entered '21 Mar 2021 13:39:15'	System	21 Mar 2021 18:39:18

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-28T12:05:58-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '735b2b6e-ca51-4589-a3be-e129b6c54655'	System	28 Mar 2021 17:07:52
User entered 'No (N)'	System	28 Mar 2021 17:07:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-28T12:06:00-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '735b2b6e-ca51-4589-a3be-e129b6c54655'	System	28 Mar 2021 17:07:52
User entered 'No (N)'	System	28 Mar 2021 17:07:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-03-28T12:06:04-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '735b2b6e-ca51-4589-a3be-e129b6c54655' User entered '28 Mar 2021 12:06:04'	System	28 Mar 2021 17:07:52
	System	28 Mar 2021 17:07:52

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-04T06:39:45-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8ec63baf-20d9-464e-9d2d-db26eb00969a'	System	04 Apr 2021 11:39:54
User entered 'No (N)'	System	04 Apr 2021 11:39:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-04T06:39:49-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8ec63baf-20d9-464e-9d2d-db26eb00969a'	System	04 Apr 2021 11:39:54
User entered 'No (N)'	System	04 Apr 2021 11:39:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-04T06:39:52-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '8ec63baf-20d9-464e-9d2d-db26eb00969a' User entered '04 Apr 2021 06:39:52'	System	04 Apr 2021 11:39:54
	System	04 Apr 2021 11:39:54

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-11T06:04:19-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7197797c-0981-4957-97df-a375e0d08275'	System	11 Apr 2021 11:04:31
User entered 'No (N)'	System	11 Apr 2021 11:04:31

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-11T06:04:22-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7197797c-0981-4957-97df-a375e0d08275'	System	11 Apr 2021 11:04:31
User entered 'No (N)'	System	11 Apr 2021 11:04:31

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-11T06:04:25-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '7197797c-0981-4957-97df-a375e0d08275' User entered '11 Apr 2021 06:04:25'	System	11 Apr 2021 11:04:31
	System	11 Apr 2021 11:04:31

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-18T06:53:56-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5deecad8-5313-4cc4-a6c7-e9aead1c956e' User entered 'No (N)'	System	18 Apr 2021 11:54:06
	System	18 Apr 2021 11:54:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-18T06:54:01-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5deecad8-5313-4cc4-a6c7-e9aead1c956e' User entered 'No (N)'	System	18 Apr 2021 11:54:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-18T06:54:03-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '5deecad8-5313-4cc4-a6c7-e9aead1c956e'	System	18 Apr 2021 11:54:06
User entered '18 Apr 2021 06:54:03'	System	18 Apr 2021 11:54:06

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-25T06:01:31-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c651c79b-1b27-45d0-8d44-65422416136d' User entered 'No (N)'	System	25 Apr 2021 11:01:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-25T06:01:34-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c651c79b-1b27-45d0-8d44-65422416136d'	System	25 Apr 2021 11:01:39
User entered 'No (N)'	System	25 Apr 2021 11:01:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-04-25T06:01:37-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'c651c79b-1b27-45d0-8d44-65422416136d'	System	25 Apr 2021 11:01:39
User entered '25 Apr 2021 06:01:37'	System	25 Apr 2021 11:01:39

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Have you had 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-05-02T10:27:25-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ca638e84-ecb7-48df-adb3-af3d96d70e7f' User entered 'No (N)'	System	02 May 2021 15:27:38
	System	02 May 2021 15:27:38

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

Have you been exposed to someone with known SARS-CoV-2 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 (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-05-02T10:27:27-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ca638e84-ecb7-48df-adb3-af3d96d70e7f' User entered 'No (N)'	System	02 May 2021 15:27:38
	System	02 May 2021 15:27:38

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-05-02T10:27:31-05:00', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: 'ca638e84-ecb7-48df-adb3-af3d96d70e7f' User entered '02 May 2021 10:27:31'	System	02 May 2021 15:27:38
	System	02 May 2021 15:27:38

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:09:47

US3752088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:09:47
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:09:47

US3752088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:25:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-28T05:08:02', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1c171acf-4ffa-464d-bacb-f99643e7b23b'	System	28 Feb 2021 11:08:11
User entered 'No (N)'	System	28 Feb 2021 11:08:11

US3752088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:25:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:58:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2203714-9D9B-4781-BA2A-6730ACB99580)', Time: '2021-02-28T05:08:06', User OID: 'PatientReportedOutcome (US3752088)', ODM File OID: '1c171acf-4ffa-464d-bacb-f99643e7b23b' User entered '28 Feb 2021 05:08:06'	System	28 Feb 2021 11:08:11
	System	28 Feb 2021 11:08:11

US3752088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:31:39

US3752088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:31:39

US3752088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:31:39

US3752088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:31:39

US3752088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:31:47

US3752088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:30:41
User entered 'I'	System	03 Nov 2020 16:31:47

US3752088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4)	10 Dec 2020 23:23:15
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '10 Dec 2020'	(b) (4)	
	Amanda Horn (b) (4)	10 Dec 2020 23:23:15
	(b) (4)	

US3752088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	10 Dec 2020 23:23:15

US3752088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered empty.	(b) (4)	10 Dec 2020 23:23:15
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4)	10 Dec 2020 23:23:19
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
User entered 'I'	System	10 Dec 2020 23:23:19

US3752088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4)	10 Jan 2021 21:32:52
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '7 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	10 Jan 2021 21:32:52
	(b) (4)	

US3752088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4)	10 Jan 2021 21:32:52

US3752088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	10 Jan 2021 21:32:52
	(b) (4)	

US3752088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	Amanda Horn (b) (4)	10 Jan 2021 21:32:57

US3752088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
User entered 'I'	System	10 Jan 2021 21:32:57

US3752088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:49:23

US3752088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
	(b) (4)	
User entered '05 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:49:23

US3752088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 21:49:23

US3752088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:11:51
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:49:23

US3752088

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:49:14

US3752088

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:25
User entered 'I'	System	09 Feb 2021 21:49:14

US3752088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:30
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:06

US3752088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:30
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:06

US3752088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:30
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:06

US3752088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'VISIT4'	System	17 Mar 2021 14:16:06

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '07:25'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '17 Mar 2021 07:25'	System	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '76'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'bpm'	System	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '16'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'breaths/min'	System	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '124'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'mmHg'	System	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:07
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '82'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'mmHg'	System	31 Mar 2021 16:30:49

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 06:02:48

US3752088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 06:02:48

US3752088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:38
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:15

US3752088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:12:38
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:15

US3752088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:24:24
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:47

US3752088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:24:24
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:47

US3752088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:24:24
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '07:38'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:47

US3752088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered '17 Mar 2021 07:38'	System	17 Mar 2021 14:16:47

US3752088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:24:55
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:16:52

US3752088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:02:48
User entered 'I'	System	17 Mar 2021 14:16:52

US3752088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	09 Apr 2021 19:03:20
	(b) (4)	

US3752088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
	(b) (4)	
User entered '9 Apr 2021'	Timothy Campbell (b) (4)	09 Apr 2021 19:03:20
	(b) (4)	

US3752088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	09 Apr 2021 19:03:20
	(b) (4)	

US3752088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	09 Apr 2021 19:03:20
	(b) (4)	

US3752088

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	09 Apr 2021 19:03:47
	(b) (4)	

US3752088

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 19:03:47

US3752088

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

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:28:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:48:42

US3752088

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

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:28:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '12 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:48:42

US3752088

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

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:28:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Clinic (Clinic)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:48:42

US3752088

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

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 19:48:42

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '12 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:59
User entered '0'	(b) (4) Haylee Rowe (b) (4)	15 Mar 2021 20:42:13
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:59:05

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:59
User entered 'Amendment 6 or later (Amendment 6 or later)'	Haylee Rowe (b) (4)	15 Mar 2021 20:42:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:59:05

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '12 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Placebo (Placebo)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Placebo (Placebo)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Placebo (Placebo)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:29:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '1'	System	25 Jan 2021 19:49:14

US3752088

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

Form: Unblinding

Generated On: 12 Aug 2021 13:25:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'I'	System	25 Jan 2021 19:49:14

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '187.9' cm	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '107.4' kg	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '30.41941'	System	17 Mar 2021 14:31:29
DataPoint set to visible.	System	25 Jan 2021 19:49:14

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '187.9' cm	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '107.4' kg	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '30.41941'	System	17 Mar 2021 14:31:29
DataPoint set to visible.	System	25 Jan 2021 19:49:14

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '12 Jan 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '09:35'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '12 Jan 2021 09:35'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '98.2' F	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '65'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'bpm'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '16'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'breaths/min'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '118'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'mmHg'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '80'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'mmHg'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '187.9' cm	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '107.4' kg	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '30.41941'	System	17 Mar 2021 14:31:29
DataPoint set to visible.	System	25 Jan 2021 19:49:14

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '12 Jan 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '10:43'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '12 Jan 2021 10:43'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '98.0' F	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '51'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'bpm'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '15'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'breaths/min'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '130'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'mmHg'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:31:23
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '70'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:29

US3752088

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'mmHg'	System	17 Mar 2021 14:31:29

US3752088

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:09
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:38

US3752088

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:09
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '12 Jan 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:31:38

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'mRNA-1273'	System	17 Mar 2021 14:32:10
DataPoint set to visible.	System	25 Jan 2021 19:49:14

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '12 Jan 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '10:13'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '12 Jan 2021 10:13'	System	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:32:51
User entered 'ONCE'	System	17 Mar 2021 14:32:10

US3752088

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

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered 'INTRAMUSCULAR'	System	17 Mar 2021 14:32:10

US3752088

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:40

US3752088

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '12 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:40

US3752088

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '09:49'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:40

US3752088

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '12 Jan 2021 09:49'	System	25 Jan 2021 19:49:40

US3752088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:50

US3752088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '12 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:50

US3752088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '09:47'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:50

US3752088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '12 Jan 2021 09:47'	System	25 Jan 2021 19:49:50

US3752088

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

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:33:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:49:53

US3752088

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

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:13:24
User entered '1'	System	25 Jan 2021 19:49:53

US3752088

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:14:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:50:08

US3752088

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:14:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered '19 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:50:08

US3752088

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:14:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:50:08

US3752088

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:14:56
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:50:08

US3752088

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:15:07
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'Yes (Y)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Jan 2021 19:50:45

US3752088

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
User entered 'I'	System	25 Jan 2021 19:50:45

US3752088

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:52:42
User entered '1'	System	25 Jan 2021 19:50:45
DataPoint set to visible.	System	25 Jan 2021 19:50:45

US3752088

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:41:34
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:49:01

US3752088

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:41:34
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '22 Feb 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:49:01

US3752088

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:41:34
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Clinic (Clinic)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:49:01

US3752088

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'OLD29'	System	17 Mar 2021 13:49:01

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '22 Feb 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '08:58'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered '22 Feb 2021 08:58'	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '98.2' F	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '76'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'bpm'	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '14'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'breaths/min'	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '130'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'mmHg'	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '78'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'mmHg'	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:42:21
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:02

US3752088

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:39:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:10:46
Query 'please provide source' answered with 'UPDATED' (Site from CRA).	Amanda Horn (b) (4)	30 Mar 2021 18:28:17
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:53:28
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	17 Mar 2021 13:50:26
User entered 'Yes (Y)' reason for change: Data Entry Error	System	17 Mar 2021 13:50:26
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	Lauren Evans (b) (4)	17 Mar 2021 13:50:21
User entered 'No (N)'	System	17 Mar 2021 13:50:21
	Lauren Evans (b) (4)	17 Mar 2021 13:50:21

US3752088

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:10:46
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '22 Feb 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:21

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	17 Mar 2021 13:50:45
	Lauren Evans (b) (4)	

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:45
DataPoint set to visible.	System	25 Jan 2021 19:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:35
User entered empty.	System	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered empty.	System	17 Mar 2021 13:50:45

US3752088

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:53:46
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 13:50:53

US3752088

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:43:26
User entered 'I'	System	17 Mar 2021 13:50:53

US3752088

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:45:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4)	
	Amanda Horn (b) (4)	24 Mar 2021 17:09:11
	(b) (4)	

US3752088

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:45:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4)	24 Mar 2021 17:09:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:45:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4)	24 Mar 2021 17:09:11
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:45:39
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'subject declined injection 2 at OL-D29, Amanda Horn no SAFETY CALL attempted'	(b) (4)	24 Mar 2021 17:09:11

US3752088

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:10:18
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'Yes (Y)'	(b) (4)	24 Mar 2021 17:09:16
	Amanda Horn (b) (4)	
	(b) (4)	

US3752088

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 17:09:16

US3752088

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:25:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:35:21
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
Signature has been broken.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:23:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Tonya Cato (b) (4)	23 Feb 2021 21:23:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	21 Sep 2020 17:18:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Amanda Horn (b) (4)	21 Sep 2020 17:14:57
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 17:06:46

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness unilateral, LLT: Hearing loss unilateral - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Feb 2021 21:32:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 21:32:04
Data point term sent to Coder	System	23 Feb 2021 21:31:34
User entered 'Right ear hearing loss'	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered 'Yes (Y)'	Tonya Cato	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered 'No (N)'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered 'No (N)'	Tonya Cato	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '17 Jan 2021'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered 'Yes (Y)'	Tonya Cato	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 14:04:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:04:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Tonya Cato (b) (4)	25 Feb 2021 14:04:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 21:31:20
User entered empty.	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 14:04:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:04:05
User entered 'No (N)' reason for change: Data Entry Error	Tonya Cato (b) (4)	25 Feb 2021 14:04:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 21:31:20
User entered empty.	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	Tonya Cato	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '0'	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 14:04:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:04:05
User entered 'Related (RELATED)' reason for change: Data Entry Error	Tonya Cato (b) (4)	25 Feb 2021 14:04:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 21:31:20
User entered empty.	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 14:04:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:04:05
User entered 'Related (RELATED)' reason for change: Data Entry Error	Tonya Cato (b) (4)	25 Feb 2021 14:04:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 21:31:20
User entered empty.	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no Dosing Discontinuation record that match this information and this AE started after the last vaccine dose. Please review and update accordingly. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:27:04
	(b) (4), (b) (6)	24 Mar 2021 17:04:07
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no Dosing Discontinuation record that match this information and this AE started after the last vaccine dose. Please review and update accordingly. Otherwise, clarify.' answered with 'dosing discontinuation has now been updated' (Site from DM).	Lauren Evans (b) (4)	17 Mar 2021 20:03:13
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no Dosing Discontinuation record that match this information and this AE started after the last vaccine dose. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:59:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	25 Feb 2021 14:05:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Feb 2021 21:31:20
User entered '0'	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered '1' reason for change: Data Entry Error	(b) (4) Tonya Cato (b) (4)	25 Feb 2021 14:05:28
User entered '0'	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:33:03
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'conProc has now been updated' (Site from DM).	Lauren Evans (b) (4)	17 Mar 2021 20:07:53
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 19:00:08
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Mar 2021 00:24:50
User entered '1' reason for change: Data Entry Error	Tonya Cato (b) (4)	25 Feb 2021 14:05:28
User entered '0'	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 14:04:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:04:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Tonya Cato (b) (4)	25 Feb 2021 14:04:05
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 21:31:20
User entered empty.	Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	(b) (4) Tonya Cato (b) (4)	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:24:50
User entered empty.	Tonya Cato	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 14:04:05

US3752088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 21:31:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Mar 2021 13:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 13:30:37
Data point term sent to Coder	System	18 Mar 2021 13:29:21
User entered 'Hypertension'	Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '01 Feb 2021'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:29:20
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'None (NONE)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'I'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 13:29:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 13:29:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Lauren Evans (b) (4)	18 Mar 2021 13:29:28
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 13:29:20
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:29:20
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 13:29:20

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:32:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:32:38
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 13:31:24
User entered 'Nausea'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '12 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
User entered empty.	System	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	18 Mar 2021 13:30:46
User entered 'No (N)' reason for change: Data Entry Error	System	18 Mar 2021 13:30:46
User closed query 'Data is required. Please complete.' (Site from System).	Lauren Evans (b) (4)	18 Mar 2021 13:30:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 13:30:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 13:30:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Evans (b) (4)	18 Mar 2021 13:30:34
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 13:30:25
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	18 Mar 2021 13:31:00
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Mar 2021 13:31:00
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 13:30:25
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:30:25
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
User entered empty.	System	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:30:25
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'None (NONE)'	(b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'l'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:31:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
User entered '0'	System	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34
User entered '0'	System	18 Mar 2021 13:30:25

US3752088

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:33:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:33:39
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 13:32:27
User entered 'Vomitting'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '12 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
User entered empty.	System	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
User entered empty.	System	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'None (NONE)'	(b) (4)	18 Mar 2021 13:31:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'I'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
User entered '0'	System	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38
User entered '0'	System	18 Mar 2021 13:31:55

US3752088

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:38

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:34:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:34:37
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 13:33:28
User entered 'Diarrhea'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '12 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
User entered empty.	System	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
User entered empty.	System	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'None (NONE)'	(b) (4)	18 Mar 2021 13:32:35
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'l'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 13:32:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 13:32:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lauren Evans (b) (4)	18 Mar 2021 13:32:42
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 13:32:35
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
User entered '0'	System	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44
User entered '0'	System	18 Mar 2021 13:32:35

US3752088

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:44

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Low grade fever - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:35:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:35:39
Data point term sent to Coder	System	18 Mar 2021 13:34:29
User entered 'Low grade fever'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:33:31
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '12 Mar 2021'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:33:31
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
User entered empty.	System	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:33:31
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
User entered empty.	System	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'None (NONE)'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'l'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
User entered '0'	System	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46
User entered '0'	System	18 Mar 2021 13:33:31

US3752088

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:46

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:35:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:35:38
Data point term sent to Coder	System	18 Mar 2021 13:34:28
User entered 'Chills'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:34:08
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '12 Mar 2021'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:34:08
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
User entered empty.	System	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
User entered empty.	System	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:33:02
User closed query 'please provide source showing severity.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:32:59
Query 'please provide source showing severity.' answered with 'UPDATED' (Site from CRA).	Amanda Horn (b) (4)	30 Mar 2021 18:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User opened query 'please provide source showing severity.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:02:07
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:34:08
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'None (NONE)'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	18 Mar 2021 13:34:25
User entered '1' reason for change: Data Entry Error	Lauren Evans (b) (4)	18 Mar 2021 13:34:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Mar 2021 13:34:08
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
User entered '0'	System	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48
User entered '0'	System	18 Mar 2021 13:34:08

US3752088

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:48

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:36:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 13:36:39
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 13:35:30
User entered 'body aches'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'No (N)'	(b) (4)	18 Mar 2021 13:35:12
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '12 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:35:12
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
User entered empty.	System	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '14 Mar 2021'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:35:12
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
User entered empty.	System	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:53:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:33:45
Query 'please provide source' answered with 'UPDATED' (Site from CRA).	Amanda Horn (b) (4)	30 Mar 2021 18:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User opened query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 17:03:02
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:35:12
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered empty.	(b) (4)	18 Mar 2021 13:35:12
	Lauren Evans (b) (4)	

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered 'None (NONE)'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User entered 'l'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered '0'	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 13:35:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 13:35:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lauren Evans (b) (4)	18 Mar 2021 13:35:23
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 13:35:12
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 17:04:07
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:49
	(b) (4)	
User entered empty.	Lauren Evans (b) (4)	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
User entered '0'	System	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50
User entered '0'	System	18 Mar 2021 13:35:12

US3752088

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:25:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:25:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:04:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	21 Sep 2020 17:10:57
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	17 Aug 2020 17:07:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INTERMITTENT HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:19:02
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INTERMITTENT HEADACHE should be recorded, and update con med indication or provide clarification. ' answered with 'THIS IS NOT A WORSENING OF THE MEDICAL HISTORY. THIS WAS FOR ONE OF THE INTERMITTENT HEADACHES AS REPORTED IN HER MEDICAL HISTORY.' (Site from DM).	Amanda Horn (b) (4) (b) (4)	08 Jan 2021 18:59:28
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INTERMITTENT HEADACHE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:34:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:13:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 15:13:00
Data point term sent to Coder	System	17 Nov 2020 15:12:30
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 15:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:13:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:13:42
Data point term sent to Coder	System	21 Sep 2020 17:12:50
User entered 'TYLENOL'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User closed query 'Per CDM Re-query: Response is noted. Kindly consider to update Indication to the Medical History Term recorded in Medical History CRF (Intermittent Headaches) so there would be an exact match.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:50:04
Query 'Per CDM Re-query: Response is noted. Kindly consider to update Indication to the Medical History Term recorded in Medical History CRF (Intermittent Headaches) so there would be an exact match.' answered with 'Changed to intermittent headache' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:12:19
User entered 'Intermittent HEADACHE' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 15:12:03
User opened query 'Per CDM Re-query: Response is noted. Kindly consider to update Indication to the Medical History Term recorded in Medical History CRF (Intermittent Headaches) so there would be an exact match.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:35:59
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:31:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this is not an AE, MH indicates subject has intermittent headaches' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:45:17
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:55:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '500'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'mg (mg)'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'as needed (PRN)'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'Oral (ORAL)'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 21:31:37
User closed query 'Per source, start date was 2020, no month or day was captured in the source. Please verify and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:31:15
Query 'Per source, start date was 2020, no month or day was captured in the source. Please verify and correct accordingly.' answered with 'data updated per query' (Site from CRA).	Lauren Evans (b) (4)	09 Apr 2021 17:08:53
Signature has been broken.	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
User entered 'UN UNK 2020' reason for change:	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
Data Entry Error		
User opened query 'Per source, start date was 2020, no month or day was captured in the source. Please verify and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:27:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:24:43
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '28 Aug 2020'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '0'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 21:33:16
DataPoint Un-verified.	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
Signature has been broken.	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	10 Apr 2021 14:04:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 21:33:03
User closed query 'No end date was captured in the source, please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:32:06
Query 'No end date was captured in the source, please verify and update accordingly.' answered with 'data updated per query' (Site from CRA).	Lauren Evans (b) (4)	09 Apr 2021 17:09:00
Signature has been broken.	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
User entered empty; reason for change Data Entry Error	Lauren Evans (b) (4)	09 Apr 2021 17:06:55
User opened query 'No end date was captured in the source, please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:28:04
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:24:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '28 Aug 2020'	Amanda Horn (b) (4)	21 Sep 2020 17:12:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User closed query 'Per DM CLR: Please review response to this field as the start/stop of the CM is not within the solicited AE timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:04:17
Query 'Per DM CLR: Please review response to this field as the start/stop of the CM is not within the solicited AE timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:47:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:47:05
User opened query 'Per DM CLR: Please review response to this field as the start/stop of the CM is not within the solicited AE timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:56:07
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	21 Sep 2020 17:12:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:12:03

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:28:23
Data point term sent to Coder	System	05 Nov 2020 19:27:45
User entered 'SEASONAL INFLUENZA VACCINATION'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'PREVENTION OF SEASONAL INFLUENZA'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '0.5'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'mL (mL)'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered 'once (ONCE)'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '23 Oct 2020'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '0'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '23 Oct 2020'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	05 Nov 2020 19:27:31
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User entered empty.	System	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User entered empty.	System	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:17
User entered empty.	System	05 Nov 2020 19:27:31

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:31
Data point term sent to Coder	System	05 Nov 2020 19:28:47
User entered 'PPSV23'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'PREVENTION OF PNEUMONIA'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '0.5'	Amanda Horn (b) (4) (b) (4)	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered 'mL (mL)'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'once (ONCE)'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered empty.	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '23 Oct 2020'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '0'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:43
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered '23 Oct 2020'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:21:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 18:05:34
User entered 'No (N)'	Amanda Horn (b) (4)	05 Nov 2020 19:28:10
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered empty.	System	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered empty.	System	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered empty.	System	05 Nov 2020 19:28:10

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 14:19:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:19:44
Data point term sent to Coder User entered 'lisinopril'	System (b) (4), (b) (6)	17 Mar 2021 14:19:06 17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '20'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 14:18:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: CORTICOSTEROIDS, ATC: CORTICOSTEROIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:41:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:41:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:19:03
Data point term sent to Coder	System	01 Apr 2021 21:05:36
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:04:45
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:04:45
User entered 'dexamethasone' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:04:45
User closed query 'Per CDM: Please update with medication/injection name if appropriate' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 22:28:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:10:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:10:32
User signature succeeded.	Priyantha Wijewardane (b) (4)	25 Mar 2021 18:36:04
Data point term sent to Coder	System	25 Mar 2021 18:16:45

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

Name of Medication

Audit	User	Time (GMT)
Query 'Per CDM: Please update with medication/injection name if appropriate' answered with 'data updated' (Site from DM). Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:16:38
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:16:23
User entered 'methylprednisone' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:16:23
User opened query 'Per CDM: Please update with medication/injection name if appropriate' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:25:19
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: CORTICOSTEROIDS, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:57:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:57:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	17 Mar 2021 20:25:50
Data point term sent to Coder	System	17 Mar 2021 14:21:10
User entered 'steroid injection to right ear drum'	(b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:47
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'right ear hearing loss'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:19:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' answered with 'updated per query' (Site from DM).	(b) (4)	
Signature has been broken.	Tonya Cato (b) (4)	06 Apr 2021 14:14:56
User entered '10' reason for change: Data Entry Error	Tonya Cato (b) (4)	06 Apr 2021 14:14:32
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:54:24
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 19:59:49
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Apr 2021 14:14:32
Signature has been broken.	Tonya Cato (b) (4)	06 Apr 2021 14:14:32
User entered 'mg (mg)' reason for change: Data Entry Error	Tonya Cato (b) (4)	06 Apr 2021 14:14:32
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	06 Apr 2021 19:59:49
	(b) (4)	
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	06 Apr 2021 19:59:49
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
	(b) (4)	
User entered 'injection'	(b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:54
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:58
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'intratympanic'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:22:59
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:01
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:23:07
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:20:24

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
User entered empty.	System	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
User entered empty.	System	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:23
User entered empty.	System	17 Mar 2021 14:20:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: CORTICOSTEROIDS, ATC: CORTICOSTEROIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:41:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:41:56
User signature succeeded.	Priyantha Wijewardane (b) (4)	03 Apr 2021 11:19:03
Data point term sent to Coder	System	01 Apr 2021 21:05:35
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:05:01
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:05:01
User entered 'dexamethasone' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:05:01
User closed query 'Per CDM: Please update with medication/injection name if appropriate' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 22:28:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:10:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:10:32
User signature succeeded.	Priyantha Wijewardane (b) (4)	25 Mar 2021 18:36:04
Data point term sent to Coder	System	25 Mar 2021 18:17:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

Name of Medication

Audit	User	Time (GMT)
Query 'Per CDM: Please update with medication/injection name if appropriate' answered with 'data updated' (Site from DM). Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:17:34
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:17:18
User entered 'methylprednisone' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	25 Mar 2021 18:17:18
User opened query 'Per CDM: Please update with medication/injection name if appropriate' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:25:34
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: CORTICOSTEROIDS, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:57:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:57:32
User signature succeeded.	Priyantha Wijewardane (b) (4)	17 Mar 2021 20:25:50
Data point term sent to Coder	System	17 Mar 2021 14:25:13
Data point term sent to Coder	System	17 Mar 2021 14:24:12
User entered 'steroid injection to right ear drum'	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:02
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'right ear hearing loss' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:19:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:06
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' answered with 'updated per query' (Site from DM).	(b) (4)	
Signature has been broken.	Tonya Cato (b) (4)	06 Apr 2021 14:19:09
User entered '10' reason for change: Data Entry Error	Tonya Cato (b) (4)	06 Apr 2021 14:18:45
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:54:33
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:07
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4)	06 Apr 2021 20:01:14
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Apr 2021 14:18:45
Signature has been broken.	Tonya Cato (b) (4)	06 Apr 2021 14:18:45
User entered 'mg (mg)' reason for change: Data Entry Error	Tonya Cato (b) (4)	06 Apr 2021 14:18:45
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	06 Apr 2021 23:21:11
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	06 Apr 2021 20:01:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4)	06 Apr 2021 20:01:14
	(b) (4)	
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
	(b) (4)	
User entered 'injection' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:12
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	17 Mar 2021 14:24:55
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'intratympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:24:55
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:24:55
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:26
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 14:24:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:24:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:24:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:23:53
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:23:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
User entered empty.	System	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
User entered empty.	System	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:32
User entered empty.	System	17 Mar 2021 14:23:53

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 18:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 18:19:29
Data point term sent to Coder	System	25 Mar 2021 18:18:48
Data point term sent to Coder	System	25 Mar 2021 15:41:18
User entered 'PREDNISONE'	Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'RIGHT EAR HEARING LOSS'	(b) (4)	
reason for change: Data Entry Error	Jamie Pettus (b) (4)	25 Mar 2021 18:18:15
User entered 'RUGHT EAR HEARING LOSS'	(b) (4)	
	Amanda Horn (b) (4)	25 Mar 2021 15:41:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '60'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:49
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:39:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'once daily (QD)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:40:01
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:40:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'Oral (ORAL)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '10 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:07
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:06
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '17 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
User entered '1'	System	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
User entered '1'	System	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:35
User entered '804 (804)'	System	25 Mar 2021 15:41:08

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:47
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:42:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:42:29
Data point term sent to Coder User entered 'PREDNISONE'	System Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19 25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'RIGHT EAR HEARING LOSS'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:42
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '40'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:39
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:35
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'once daily (QD)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'Oral (ORAL)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	25 Mar 2021 15:41:48
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:26
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '18 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '20 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:20
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
User entered '1'	System	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
User entered '1'	System	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:46
User entered '804 (804)'	System	25 Mar 2021 15:41:48

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:43:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:43:27
Data point term sent to Coder User entered 'PREDNISONE'	System Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:22 25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:54
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:41:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'RIGHT EAR HEARING LOSS'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:02
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '20'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'mg (mg)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:06
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'once daily (QD)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'Oral (ORAL)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:12
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	25 Mar 2021 15:42:19
	(b) (4)	

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '21 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '0'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:18
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered '23 Feb 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:07:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 16:42:20
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:44
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:04
User entered 'No (N)'	(b) (4) Amanda Horn (b) (4) (b) (4)	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
User entered '1'	System	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
User entered '1'	System	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:25:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:50
User entered '804 (804)'	System	25 Mar 2021 15:42:19

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:25:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:12
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:11:03
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
Signature has been broken.	(b) (4)	17 Mar 2021 20:04:37
	Lauren Evans (b) (4)	17 Mar 2021 20:04:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Evans (b) (4)	17 Mar 2021 20:04:37
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:15:34
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	09 Mar 2021 21:05:07

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:25:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '22 Jan 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:07:28

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:25:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Hyperbaric chamber- 38 hours of treatment'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:07:28

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Adverse Event (AE)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:07:28

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:25:13

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	17 Mar 2021 20:07:28
	Lauren Evans (b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:25:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered '12 Mar 2021'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:08:59

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:25:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Covid-19 PCR test- negative'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:08:59

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered 'Adverse Event (AE)'	(b) (4) Lauren Evans (b) (4)	17 Mar 2021 20:08:59

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 12 Aug 2021 13:25:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:25:50
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	17 Mar 2021 20:08:59

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:25:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '03 Feb 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:05:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:25:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'DEXAMETHASONE PERFUSION	(b) (4)	
right ear' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Apr 2021 21:06:47
User entered 'dexamethasone perfusion'	(b) (4)	
	Jamie Pettus (b) (4)	01 Apr 2021 21:05:59
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'Adverse Event (AE)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:05:59

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 12 Aug 2021 13:25:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	01 Apr 2021 21:05:59
	(b) (4)	

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 12 Aug 2021 13:25:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:25
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered '10 Feb 2021'	(b) (4) Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:06:17

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 12 Aug 2021 13:25:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:25
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'DEXAMETHASONE PERFUSION	(b) (4)	
right ear' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Apr 2021 21:06:25
User entered 'dexamethasone perfusion'	(b) (4)	
	Jamie Pettus (b) (4)	01 Apr 2021 21:06:17
	(b) (4)	

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 12 Aug 2021 13:25:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:25
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered 'Adverse Event (AE)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	01 Apr 2021 21:06:17

US3752088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 12 Aug 2021 13:25:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:25
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:08:17
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:19:03
User entered empty.	(b) (4)	
	Jamie Pettus (b) (4)	01 Apr 2021 21:06:17
	(b) (4)	