

US3772037 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:46:50

All time stamps listed in this document are displayed in GMT

US3772037

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

[Participant ID](#)

US3772037

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

US3772037

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3772037

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE) (SENSORY)
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	ASTHMA (MODERATE)
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	RIGHT ANKLE FRACTURE
Start date (dd MMM yyyy)	19 SEP 2012
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)	19 SEP 2012
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1975
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 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Condition	COSMETIC BOTOX FACIAL INJECTION
Start date (dd MMM yyyy)	UN MAR 2017
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 MAR 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:10
Height (<i>xxx.x</i>)	155 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	34.13111 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) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 05:10:05

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Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1992

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 05:10:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185097

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) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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)	11 AUG 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:10
Temperature (xxx.x)	35.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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)	11 AUG 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:40
Temperature (xxx.x)	36.7 C
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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 10:04

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) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

09:38 (24 HR)

Collection date and time (derived)

11 AUG 2020 09:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:44	11 AUG 2020 09:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

11 AUG 2020 10:43

PC Open Date & Time

11 AUG 2020 10:24

PC Close Date & Time

11 AUG 2020 12:54

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 98.0 °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 AUG 2020 18:32
PC Open Date & Time	11 AUG 2020 13:49
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:28

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	13 AUG 2020 18:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

97.5 °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

14 AUG 2020 18:36

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

15 AUG 2020 18:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

16 AUG 2020 19:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 18:11

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020 10:47

PC Open Date & Time

11 AUG 2020 10:24

PC Close Date & Time

11 AUG 2020 12:54

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

11 AUG 2020 18:33

PC Open Date & Time

11 AUG 2020 13:49

PC Close Date & Time

12 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 ☐

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

5

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

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

Yes ☐

No ☒

Please record - **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

12 AUG 2020 18:31

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 ☐

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

1

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

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

Yes ☐

No ☒

Please record - **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 AUG 2020 18:39

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020 18:36

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020 18:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020 19:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 AUG 2020 18:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 10:47
PC Open Date & Time	11 AUG 2020 10:24
PC Close Date & Time	11 AUG 2020 12:54

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:34
PC Open Date & Time	11 AUG 2020 13:49
PC Close Date & Time	12 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

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
EAB) (1725)

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US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:37
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

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)

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:09
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT NOTIFIED ME THAT
SHE ACCIDENTALLY MARKED
HEADACHE AS A SYMPTOM ON
DAY 1. SO THIS IS A FALSE SIDE
EFFECT.

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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)	08 SEP 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:59
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:22

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

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

11:03 (24 HR)

Collection date and time (derived)

08 SEP 2020 11:03

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	08 SEP 2020 11:06
Nasopharyngeal Swab 2	No		

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

08 SEP 2020 11:59

PC Open Date & Time

08 SEP 2020 11:42

PC Close Date & Time

08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

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

PC Time Stamp	08 SEP 2020 17:50
PC Open Date & Time	08 SEP 2020 15:07
PC Close Date & Time	09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

98.0 °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

10 SEP 2020 17:41

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

98.1 °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

11 SEP 2020 18:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 SEP 2020 20:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 14:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

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.

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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

15 SEP 2020 11:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:00

PC Open Date & Time

08 SEP 2020 11:42

PC Close Date & Time

08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

08 SEP 2020 17:51

PC Open Date & Time

08 SEP 2020 15:07

PC Close Date & Time

09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 ☐

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

1

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

10 SEP 2020 17:42

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

11 SEP 2020 18:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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

12 SEP 2020 20:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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

13 SEP 2020 14:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

15 SEP 2020 11:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:00
PC Open Date & Time	08 SEP 2020 11:42
PC Close Date & Time	08 SEP 2020 14:12

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:51
PC Open Date & Time	08 SEP 2020 15:07
PC Close Date & Time	09 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:27
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

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EAB) (1725)

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:42
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 ☒

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:17
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 ☒

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EAB) (1725)

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 14:07
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

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EAB) (1725)

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:45

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:40
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

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.

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:00

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:36:46

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 07:42:55

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

18 OCT 2020 07:46:24

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

25 OCT 2020 14:24:44

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input 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"/>

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

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



Date and time of submission

08 NOV 2020 02:48:22

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 10:28:08

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 02:58:33

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 16:57:09

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 22:04:24

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 05:00:28

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

17 DEC 2020 00:03:14

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

24 DEC 2020 06:54:26

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

31 DEC 2020 07:32:35

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

08 JAN 2021 07:00:17

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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	14 JAN 2021 07:02:16
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 08:29:33
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

28 JAN 2021 10:21:28

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

04 FEB 2021 14:04:37

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 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 FEB 2021 13:05:34
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

18 FEB 2021 06:38:58

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 FEB 2021 09:04:16
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

04 MAR 2021 00:37:51

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

11 MAR 2021 00:02:21

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

18 MAR 2021 06:43:08

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

25 MAR 2021 15:32:13

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

01 APR 2021 04:58:43

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

10 APR 2021 15:55:52

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

15 APR 2021 09:18:41

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

22 APR 2021 04:17:24

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

29 APR 2021 12:47:19

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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°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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐
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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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="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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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°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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐
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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐
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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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°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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐ 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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐ 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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐
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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
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Patient Cloud Close Date & Time	17 OCT 2022 23:59
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US3772037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:46:50

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
Yes	Yes	28 FEB 2021 09:04:41

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 05:10:05

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 02:31:10

Generated On: 10 Jun 2021 09:46:50

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3772037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

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.

US3772037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	13:50 (24 HR)
Collection date and time (derived)	17 MAR 2021 13:50

US3772037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:38

Generated On: 10 Jun 2021 09:46:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772037

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:38

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772037

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Date of Contact	9 NOV 2020
Time of Contact	09:53
Date and Time of Contact (derived)	9 NOV 2020 09:53
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Date of Visit 9 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Date of Test 6 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☐
Nasal Swab ☒
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☒
No ☐

If yes, provide lab information below

Lab/ Institution Test Performed LAB24
475 KNOLLOCREST DRIVE.
REDDING, CA 96002

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 7 NOV 2020

End Date 12 NOV 2020

Oxygen Saturation 88 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☒ No ☐

Start Date 08 NOV 2020

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

Start Date _____

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

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

Ventilator Support:

High-Flow Oxygen?

Yes ☒

No ☐

Start Date

08 NOV 2020

End Date

10 NOV 2020

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Date of Contact	13 NOV 2020
Time of Contact	14:00
Date and Time of Contact (derived)	13 NOV 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	36.2 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	36.5 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	36.7 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 NOV 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	36.7 C
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 22:45:08

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	36.2 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 22:45:08

Generated On: 10 Jun 2021 09:46:50

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

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Apr 2021 19:45:05

Generated On: 10 Jun 2021 09:46:50

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	Yes	17 NOV 2020
Day 7	Yes	19 NOV 2020
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 14:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3772037

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

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 SICKD28

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

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.

US3772037

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3772037

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

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

Visit date (dd MMM yyyy)	08 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3772037

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 02:52:39

Generated On: 10 Jun 2021 09:46:50

Date of updated informed consent (dd MMM yyyy) 08 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 08 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3772037

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 JAN 2021

Collection time (00:00-23:59)

11:38 (24 HR)

Collection date and time (derived)

08 JAN 2021 11:38

US3772037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	11:40
Collection Date and Time (derived)	08 JAN 2021 11:40

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

AEID	USA-US107-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE DUE TO COVID-19 INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

SUBJECT WAS CONTACTED REGARDING SAFETY REPORT OF COVID EXPOSURE AND SYMPTOMS. THE SUBJECT REPORTED BEING TESTED FOR COVID ON THE SAME DAY THEY WERE DX WITH SINUSITIS (05 NOV 2020) AND RECEIVING A POSITIVE RESULT ON 07 NOV 2020. THE SUBJECT WAS ADVISED TO GO TO THE HOSPITAL IF THEIR OXYGEN SATURATION WAS BELOW 90. THE SUBJECT REPORTED HAVING AN O2 SATURATION OF 88 ON 8TH OF NOVEMBER. SELF REFERRED TO ER. THE SUBJECT WAS ADMITTED AS AN INPATIENT ON 08 NOV 2020. MEDICAL RECORDS HAVE BEEN REQUESTED FOR COVID TEST RESULTS AND HOSPITAL STAY.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

AEID	USA-US107-2020-MRNA-1273-P30 1000002
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	6 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 05:10:02

Generated On: 10 Jun 2021 09:46:50

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BOTH PER SUBJECT REPORT AND EXTERNAL LAB RECORDS, SUBJECT HAS POSITIVE COVID 19 INFECTION.
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)	
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Feb 2021 05:10:02

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AEID	
Adverse event	SINUSITIS
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)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Feb 2021 05:10:02

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

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 05:10:03

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication KYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY (RIGHT ANKLE)

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 160/4.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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)	27 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)		27 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"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication DEXAMETHASONE
(DECADRON) (6MG / 1.5ML)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 300

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)

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 200

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)

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 05 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6

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 (13)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication SUPPLEMENTAL OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1

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

If dose unit is Other, specify LITER

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 CONTINUOUS

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 (14)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)		08 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Name of Medication DUONEB TREATMENT
(IPRATROPIUM BROMIDE/
ALBUTEROL SULFATE)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.5/3/3

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

If dose unit is Other, specify MG/MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 NOV 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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 05:10:03

Generated On: 10 Jun 2021 09:46:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3772037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:46:50

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3772037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:46:50

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 ☐

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/NOV/2020 10:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/NOV/2020 19:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/NOV/2020 11:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/NOV/2020 16:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/DEC/2020 07:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/DEC/2020 12:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/JAN/2021 17:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Feb 2021 05:10:04

Generated On: 10 Jun 2021 09:46:50

SAEID	USA-US107-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/FEB/2021 13:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3772037 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772037

Form: Participant Creation

Generated On: 10 Jun 2021 09:46:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'US3772037'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:42

US3772037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:16
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:16
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:43

US3772037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:16
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'SCRN'	System	11 Aug 2020 17:13:31

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:44

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '72'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'YEARS'	System	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '72'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User closed query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:27:39
Query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' answered with 'entry error updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:22:29
User entered 'Female (F)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:22:19
User opened query 'Per GCL Lab Recon: GCL recorded the sex as female; However, EDC records sex as male. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 01:55:05
User entered 'Male (M)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered 'I'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:22
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:13:48

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Aug 2020'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2020'	System	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered 'Amendment 2 (2)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:09

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:32
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:04:43

US3772037

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'I'	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 00:43:36
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:46:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:06
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:31

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:19
Data point term sent to Coder	System	11 Aug 2020 17:14:59
User entered 'Hypokalemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2010'	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2010'	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:14:56

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:16
Data point term sent to Coder	System	11 Aug 2020 17:16:01
User entered 'Hyperlipidemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2010'	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2010'	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:15:27

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:18:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:18:22
Data point term sent to Coder	System	11 Aug 2020 17:17:03
User entered 'Hypertension'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2010'	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2010'	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:16:28

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:19:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:19:10
Data point term sent to Coder	System	11 Aug 2020 17:18:04
User entered 'Hypothyroidism'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2010'	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2010'	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:17:40

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:17:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:17:05
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	09 Nov 2020 23:38:03
' (Site from DM).		
Data point term sent to Coder	System	05 Nov 2020 22:34:14
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	05 Nov 2020 22:34:08
' answered with 'Updated' (Site from DM).		
User entered 'NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE) (Sensory)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Nov 2020 22:33:56
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Oct 2020 10:15:33
' (Site from DM).		
Data point term sent to Coder	System	15 Sep 2020 22:56:20

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
User closed query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' (Site from System).	System	15 Sep 2020 22:55:57
Query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' answered with 'Updated confirmed via TC with subject' (Site from System).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:57
Data point term sent to Coder	System	15 Sep 2020 22:52:12
User entered 'NUEROPATHY (DUE TO RIGHT ANKLE FRACTURE)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:51:11
User opened query 'For coding purposes, please split NUEROPATHY DUE TO RIGHT ANKLE FRACTURE into separate entries. 1. RIGHT ANKLE FRACTURE and 2. NEUROPATHY [DUE TO RIGHT ANKLE FRACTURE]' (Site from System).	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:49:30
Data point term sent to Coder	System	11 Aug 2020 17:19:06
User entered 'Nueropathy due to right ankle fracture'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2014'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2014'	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2014'	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:18:52

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User closed query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' (Site from CRA).	(b) (4), (b) (6)	01 Nov 2020 23:53:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:54:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:54:17
Data point term sent to Coder	System	26 Oct 2020 16:26:41
Query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' answered with 'updated' (Site from CRA).	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:51
Coding entries removed.	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:42
User entered 'ASTHMA (Moderate)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:25:42
User opened query '22Oct2020(b) (6):Please confirm asthma severity. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 06:54:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
Data point term sent to Coder	System	11 Aug 2020 17:20:06
User entered 'Asthma'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 2015'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 2015'	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2015'	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	11 Aug 2020 17:19:31

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 15:50:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:21:12
Data point term sent to Coder	System	11 Aug 2020 17:20:07
User entered 'Complete Hysterectomy'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '1992'	System	11 Aug 2020 17:19:49

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 22:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 22:57:54
Data point term sent to Coder	System	15 Sep 2020 22:56:17
User entered 'Right Ankle Fracture'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '19 Sep 2012'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '19 Sep 2012'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:21
User entered '0'	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Sep 2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Sep 2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2012'	System	15 Sep 2020 22:55:35

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Feb 2021 19:32:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 19:32:03
Data point term sent to Coder	System	17 Feb 2021 19:31:04
User entered 'Endometriosis'	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'un UNK 1975'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'un UNK 1992'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 1975'	System	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '1975'	System	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Jan 1992'	System	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '1992'	System	17 Feb 2021 19:30:32

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 07:15:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:15:18
Data point term sent to Coder	System	02 Apr 2021 16:24:07
User entered 'Cosmetic Botox Facial Injection'	Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered 'un Mar 2017'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered 'un Mar 2017'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:34:57
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Mar 2017'	System	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2017'	System	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'Mar 2017'	System	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '2017'	System	02 Apr 2021 16:23:44

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered '09:10'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '11 Aug 2020 09:10'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered '155' cm	Emily Crews (b) (4)	11 Aug 2020 17:20:37
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered '82' kg	Emily Crews (b) (4)	11 Aug 2020 17:20:37
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Amendment Manager: User entered '34.13111'	System	16 Sep 2020 23:51:43
User entered '34.1'	System	11 Aug 2020 17:20:37
DataPoint set to visible.	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'kg/m2'	System	11 Aug 2020 17:20:37
DataPoint set to visible.	System	11 Aug 2020 17:14:14

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User closed query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 17:33:36
Query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:57:38
User opened query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:50:50
User entered '35.9' C	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered empty; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:57:38
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '64'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'bpm'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:57:38
User entered '18'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'breaths/min'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:57:38
User entered '122'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'mmHg'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:57:38
User entered '76'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered 'mmHg'	System	11 Aug 2020 17:20:37

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:28:12

US3772037

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:28:12

US3772037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:36
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:19

US3772037

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:45:36
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:29:02
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 18:08:17
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:19

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:39
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:41
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:35:11
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 08:44:41
Query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'Added updated medical condition to MH' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 19:32:27
User opened query 'Per DM CLR: Note, 'If No, what is the reason?' = Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:34:06
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 08:07:08
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	29 Dec 2020 23:05:46
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'Complete Hysterectomy ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:17:46

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

If No, what is the reason?

Audit	User	Time (GMT)
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	29 Dec 2020 20:16:44
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	29 Dec 2020 20:16:44
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 20:16:44
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	23 Dec 2020 20:18:43
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	23 Dec 2020 20:18:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	Marisol Corrales (b) (4)	23 Dec 2020 20:18:43
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	(b) (4)	23 Dec 2020 20:16:19
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	System	23 Dec 2020 20:16:19
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	Marisol Corrales (b) (4)	23 Dec 2020 20:16:19
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	18 Dec 2020 18:00:00
	(b) (4)	26 Oct 2020 16:23:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Partner medically sterile or Other has been entered, however specify is missing. Please provide.' (Site from System).	(b) (4) System	29 Dec 2020 20:16:44
User opened query 'Partner medically sterile or Other has been entered, however specify is missing. Please provide.' (Site from System).	System	23 Dec 2020 20:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:46:44
User entered empty.	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

US3772037

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:35:11
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4)	29 Dec 2020 23:05:46
User entered 'un UNK 1992' reason for change: Data Entry Error	System	29 Dec 2020 23:05:46
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	Emily Crews (b) (4)	29 Dec 2020 23:05:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	29 Dec 2020 20:18:07
User entered empty; reason for change Data Entry Error	System	29 Dec 2020 20:18:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 20:18:07
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	29 Dec 2020 20:17:11
DataPoint Un-verified.	System	29 Dec 2020 20:17:11
User entered ' 1992' (non-conformant).	(b) (4), (b) (6)	29 Dec 2020 20:17:11
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	29 Dec 2020 20:16:44
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	23 Dec 2020 20:18:43
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	23 Dec 2020 20:16:19
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:46:49
User entered empty.	Emily Crews (b) (4)	26 Oct 2020 16:23:23
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:53
User entered '0'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:35:11
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	29 Dec 2020 23:05:46
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	29 Dec 2020 23:05:46
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:46:55
User entered 'un UNK 1992'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:50

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:00
User entered '0'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 16:23:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

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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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

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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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered 'I'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:46:31
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:49

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:11
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:11
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:11
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'VISIT1'	System	11 Aug 2020 17:22:20

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:39:09

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:34:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:34:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 16:39:09
User entered '185097' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:39:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:39:09

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:22:40

US3772037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:16
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 21:06:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:50:01
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:14
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:51:17
User entered '155' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:50:01
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:14
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:51:17
User entered '155' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '09:10'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '11 Aug 2020 09:10'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 09:35:57
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Emily Crews (b) (4) (b) (4)	18 Sep 2020 21:15:56
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:51:43
User entered '35.9' C	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '64'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'bpm'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '18'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'breaths/min'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '122'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '76'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:50:01
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:14
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:51:17
User entered '155' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 22:58:14
User entered '82' kg	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:11:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:11:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:11:28
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:23:56
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '11 Aug 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:38:08
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).		11 Aug 2020 18:11:28
User entered '10:40' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:11:28
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '11 Aug 2020 10:40'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '36.7' C reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '65' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'bpm'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '20' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'breaths/min'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '124' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:27
User entered '64' reason for change: Data Entry Error	Emily Crews (b) (4)	11 Aug 2020 18:11:28
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:23:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	11 Aug 2020 18:11:28
User entered empty.	System	11 Aug 2020 17:23:56

US3772037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:33
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:08

US3772037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:33
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered '10:04'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '11 Aug 2020 10:04'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:07:16
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:33:34
User entered 'Left Arm (LEFT ARM)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:47:39
User entered 'ONCE'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 17:21:08

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:46
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:46
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:46
User entered '09:38'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '11 Aug 2020 09:38'	System	11 Aug 2020 17:24:21

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:46:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:53
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:53
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:53
User entered '09:44'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '11 Aug 2020 09:44'	System	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:53
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:47:53
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered empty.	System	11 Aug 2020 17:24:33

US3772037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:00
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:38

US3772037

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '1'	System	11 Aug 2020 17:24:38

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:42:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576' User entered 'Yes (Y)'	System	11 Aug 2020 17:43:11
	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:42:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576' User entered '98.1'	System	11 Aug 2020 17:43:11
	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:43:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576'	System	11 Aug 2020 17:43:11
User entered 'No (N)'	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:43:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8187e5e3-7b4b-408e-9f44-19768cf95576' User entered '11 Aug 2020 10:43'	System	11 Aug 2020 17:43:11
	System	11 Aug 2020 17:43:11

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246' User entered 'Yes (Y)'	System	12 Aug 2020 01:33:03
	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246' User entered '98.0'	System	12 Aug 2020 01:33:03
	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered 'No (N)'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:32:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd97cf25e-8e41-43ea-92d2-20225e33b246'	System	12 Aug 2020 01:33:03
User entered '11 Aug 2020 18:32'	System	12 Aug 2020 01:33:03

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:27:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a' User entered 'Yes (Y)'	System	13 Aug 2020 01:28:09
	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:27:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a' User entered '99.4'	System	13 Aug 2020 01:28:09
	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a' User entered 'No (N)'	System	13 Aug 2020 01:28:09
	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7149b014-193a-4a94-90c7-274f68620a7a' User entered '12 Aug 2020 18:28'	System	13 Aug 2020 01:28:09
	System	13 Aug 2020 01:28:09

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:37:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775' User entered 'Yes (Y)'	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:37:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775' User entered '97.2'	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	System	14 Aug 2020 01:38:39
User entered 'Yes (Y)'	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with subject, conmed updated ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 17:47:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Emily Crews (b) (4)	14 Aug 2020 15:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775'	(b) (4)	
User entered '1'	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775' User entered '0'	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0f71d1e9-07a9-4d30-bad2-e329ed89a775' User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:39
	System	14 Aug 2020 01:38:39

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4' User entered 'Yes (Y)'	System	15 Aug 2020 01:36:30
	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4' User entered '97.5'	System	15 Aug 2020 01:36:30
	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4'	System	15 Aug 2020 01:36:30
User entered 'No (N)'	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bfb1edd0-b2c2-43a1-bcdd-eb9eba6eb7d4' User entered '14 Aug 2020 18:36'	System	15 Aug 2020 01:36:30
	System	15 Aug 2020 01:36:30

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6' User entered 'Yes (Y)'	System	16 Aug 2020 01:32:51
	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6' User entered '98.1'	System	16 Aug 2020 01:32:51
	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6' User entered 'No (N)'	System	16 Aug 2020 01:32:51
	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:32:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '96ddd206-29a4-474a-8f1d-08f379d882f6' User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:32:51
	System	16 Aug 2020 01:32:51

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881' User entered 'Yes (Y)'	System	17 Aug 2020 02:08:49
	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881' User entered '98.1'	System	17 Aug 2020 02:08:49
	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881'	System	17 Aug 2020 02:08:49
User entered 'No (N)'	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '98e86745-d53f-4eeb-a877-e5626e380881' User entered '16 Aug 2020 19:08'	System	17 Aug 2020 02:08:49
	System	17 Aug 2020 02:08:49

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d' User entered 'Yes (Y)'	System	18 Aug 2020 01:11:47
	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d' User entered '98.0'	System	18 Aug 2020 01:11:47
	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d'	System	18 Aug 2020 01:11:47
User entered 'No (N)'	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7f48d62d-5871-4621-a6a6-882e48f89e5d' User entered '17 Aug 2020 18:11'	System	18 Aug 2020 01:11:47
	System	18 Aug 2020 01:11:47

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7' User entered 'No (N)'	System	11 Aug 2020 17:47:05
	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'No (N)'	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:46:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '89bca285-e94b-4cf8-9326-32191a454ee7'	System	11 Aug 2020 17:47:05
User entered '11 Aug 2020 10:47'	System	11 Aug 2020 17:47:05

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'No (N)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'No (N)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered 'None (1)'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8a6955f7-af73-4c7f-95c6-d74165b3ab82'	System	12 Aug 2020 01:33:34
User entered '11 Aug 2020 18:33'	System	12 Aug 2020 01:33:34

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:28:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:29:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07' User entered 'Yes (Y)'	System	13 Aug 2020 01:31:53
	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07' User entered '5'	System	13 Aug 2020 01:31:53
	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07' User entered 'No (N)'	System	13 Aug 2020 01:31:53
	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07' User entered 'None (1)'	System	13 Aug 2020 01:31:53
	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5d9a970d-9ae7-48ea-84bc-844187136e07'	System	13 Aug 2020 01:31:53
User entered '12 Aug 2020 18:31'	System	13 Aug 2020 01:31:53

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:38:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d'	System	14 Aug 2020 01:39:48
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered 'Yes (Y)'	System	14 Aug 2020 01:39:48
	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered '1'	System	14 Aug 2020 01:39:48
	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered 'No (N)'	System	14 Aug 2020 01:39:48
	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered 'None (1)'	System	14 Aug 2020 01:39:48
	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:39:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e0d889f2-8181-4557-82d1-294b20ec745d' User entered '13 Aug 2020 18:39'	System	14 Aug 2020 01:39:48
	System	14 Aug 2020 01:39:48

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'None (1)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'No (N)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038' User entered 'No (N)'	System	15 Aug 2020 01:36:49
	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered 'None (1)'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '67da81af-5eda-4458-81b2-ac03f4b15038'	System	15 Aug 2020 01:36:49
User entered '14 Aug 2020 18:36'	System	15 Aug 2020 01:36:49

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'None (1)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'No (N)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'No (N)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered 'None (1)'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1e05e102-bf42-4c77-8191-b9542c2aea82'	System	16 Aug 2020 01:33:26
User entered '15 Aug 2020 18:33'	System	16 Aug 2020 01:33:26

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084' User entered 'None (1)'	System	17 Aug 2020 02:09:01
	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084' User entered 'No (N)'	System	17 Aug 2020 02:09:01
	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084' User entered 'No (N)'	System	17 Aug 2020 02:09:01
	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:08:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084' User entered 'None (1)'	System	17 Aug 2020 02:09:01
	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4009f9ce-9e7b-4717-9a4d-d2c446de0084' User entered '16 Aug 2020 19:09'	System	17 Aug 2020 02:09:01
	System	17 Aug 2020 02:09:01

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:11:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0' User entered 'None (1)'	System	18 Aug 2020 01:12:15
	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0' User entered 'No (N)'	System	18 Aug 2020 01:12:15
	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0' User entered 'No (N)'	System	18 Aug 2020 01:12:15
	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0' User entered 'None (1)'	System	18 Aug 2020 01:12:15
	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd583b0f9-3b0f-4c22-8205-6da4140202f0' User entered '17 Aug 2020 18:12'	System	18 Aug 2020 01:12:15
	System	18 Aug 2020 01:12:15

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd'	System	11 Aug 2020 17:47:58
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'None (0)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered 'No (N)'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T10:47:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'eaf24b65-c0a8-4f24-aa93-9045501253bd' User entered '11 Aug 2020 10:47'	System	11 Aug 2020 17:47:58
	System	11 Aug 2020 17:47:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 10:24'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 12:54'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:33:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157' User entered 'None (0)'	System	12 Aug 2020 01:34:19
	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered 'No (N)'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-11T18:34:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '413fd8c1-3a31-4d5d-a3fa-b70edba76157'	System	12 Aug 2020 01:34:19
User entered '11 Aug 2020 18:34'	System	12 Aug 2020 01:34:19

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Aug 2020 13:49'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 2'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:31:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c' User entered 'None (0)'	System	13 Aug 2020 01:32:16
	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered 'No (N)'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-12T18:32:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '750f0f6d-ae0b-4799-91f3-4e935eabc59c'	System	13 Aug 2020 01:32:16
User entered '12 Aug 2020 18:32'	System	13 Aug 2020 01:32:16

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 3'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'None (0)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:40:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered 'No (N)'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-13T18:41:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '97253077-d432-49c4-8530-0cf41b40e17a' User entered '13 Aug 2020 18:41'	System	14 Aug 2020 01:41:18
	System	14 Aug 2020 01:41:18

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 4'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:36:59', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'None (0)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered 'No (N)'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-14T18:37:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8dbb22f0-1a54-4185-a4a6-c12100b2990c' User entered '14 Aug 2020 18:37'	System	15 Aug 2020 01:37:08
	System	15 Aug 2020 01:37:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 5'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'None (0)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered 'No (N)'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-15T18:33:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc98d6b8-4e53-4e41-a2e0-f68584d21bfe' User entered '15 Aug 2020 18:33'	System	16 Aug 2020 01:33:47
	System	16 Aug 2020 01:33:47

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 6'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859' User entered 'None (0)'	System	17 Aug 2020 02:09:27
	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered 'No (N)'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-16T19:09:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'b01b564f-d3b5-4617-abe2-ff6348f78859'	System	17 Aug 2020 02:09:27
User entered '16 Aug 2020 19:09'	System	17 Aug 2020 02:09:27

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 7'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452' User entered 'None (0)'	System	18 Aug 2020 01:12:58
	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452' User entered 'None (0)'	System	18 Aug 2020 01:12:58
	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452' User entered 'None (0)'	System	18 Aug 2020 01:12:58
	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:42', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'None (0)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered 'No (N)'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-08-17T18:12:54', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9f024b29-7841-435b-bcc3-a51ba5304452'	System	18 Aug 2020 01:12:58
User entered '17 Aug 2020 18:12'	System	18 Aug 2020 01:12:58

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 17:21:08

US3772037

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:23
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:23
User entered 'Patient notified me that she accidentally marked headache as a symptom on Day 1. So this is a false side effect.'	(b) (4), (b) (6)	18 Aug 2020 18:41:02

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 18:41:08

US3772037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	18 Aug 2020 18:41:08

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:36
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:36
User entered '25 Aug 2020'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:36
User entered 'Contact Made (CONTACT MADE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:36
User entered empty.	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:35

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:41
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 17:59:42

US3772037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	08 Sep 2020 17:59:42

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:50
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:50
User entered '01 Sep 2020'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:50
User entered 'Contact Made (CONTACT MADE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:50
User entered empty.	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:29

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:48:55
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 18:00:36

US3772037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	08 Sep 2020 18:00:36

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:00
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'VISIT2'	System	08 Sep 2020 18:08:17

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '10:45'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '08 Sep 2020 10:45'	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '36.5' C reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '72' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'bpm'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '18' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'breaths/min'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '128' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:20:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:20:54
User entered '62' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Sep 2020 21:20:54
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '08 Sep 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '11:59' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '36.5' C reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '66' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'bpm'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '16' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'breaths/min'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '119' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:07
User entered '76' reason for change: Data Entry Error	Emily Crews (b) (4)	08 Sep 2020 21:20:54
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	08 Sep 2020 21:20:54
User entered empty.	System	08 Sep 2020 18:09:35

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:10:32

US3772037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:16
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:10:32

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered '11:22'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:27
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 19:07:16
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	08 Sep 2020 19:07:16
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 19:07:01
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:07:01
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 18:33:34
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	08 Sep 2020 18:33:34
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 18:32:52
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:32:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:49:27
User entered 'ONCE'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:32:40

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:32
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:32
User entered '11:03'	(b) (4), (b) (6)	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '08 Sep 2020 11:03'	System	08 Sep 2020 18:33:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:46:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:38
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:38
User entered '11:06'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '08 Sep 2020 11:06'	System	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:38
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:38
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered empty.	System	08 Sep 2020 18:34:12

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:43
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:31:55

US3772037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	08 Sep 2020 20:31:55

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9' User entered 'Yes (Y)'	System	08 Sep 2020 18:59:47
	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9' User entered '97.7'	System	08 Sep 2020 18:59:47
	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9' User entered 'No (N)'	System	08 Sep 2020 18:59:47
	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '588670b5-ed8c-44f2-9b7c-6a290f9d8cd9' User entered '08 Sep 2020 11:59'	System	08 Sep 2020 18:59:47
	System	08 Sep 2020 18:59:47

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2' User entered 'Yes (Y)'	System	09 Sep 2020 00:51:03
	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:53', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2' User entered '97.4'	System	09 Sep 2020 00:51:03
	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2'	System	09 Sep 2020 00:51:03
User entered 'No (N)'	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:50:59', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '87e098ac-b111-4657-9c2f-9e51ec5155c2' User entered '08 Sep 2020 17:50'	System	09 Sep 2020 00:51:03
	System	09 Sep 2020 00:51:03

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf' User entered 'Yes (Y)'	System	09 Sep 2020 23:25:05
	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:53', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf' User entered '99.4'	System	09 Sep 2020 23:25:05
	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:24:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf'	System	09 Sep 2020 23:25:05
User entered 'No (N)'	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8c40974c-1aef-41ee-a298-1e814153cdbf' User entered '09 Sep 2020 16:25'	System	09 Sep 2020 23:25:05
	System	09 Sep 2020 23:25:05

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f' User entered 'Yes (Y)'	System	11 Sep 2020 00:41:04
	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f' User entered '98.0'	System	11 Sep 2020 00:41:04
	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:40:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f' User entered 'No (N)'	System	11 Sep 2020 00:41:04
	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2c2c8043-b50e-4fd1-aa26-9ae25268834f' User entered '10 Sep 2020 17:41'	System	11 Sep 2020 00:41:04
	System	11 Sep 2020 00:41:04

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered 'Yes (Y)'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371' User entered '98.1'	System	12 Sep 2020 01:00:53
	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered 'No (N)'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5ed6cd60-57e1-48c1-8355-17453b2bb371'	System	12 Sep 2020 01:00:53
User entered '11 Sep 2020 18:00'	System	12 Sep 2020 01:00:53

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:18', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered 'Yes (Y)'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261' User entered '98.5'	System	13 Sep 2020 03:16:32
	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered 'No (N)'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '7d4584e2-2d0b-42ce-8c10-73926a28b261'	System	13 Sep 2020 03:16:32
User entered '12 Sep 2020 20:16'	System	13 Sep 2020 03:16:32

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970' User entered 'Yes (Y)'	System	13 Sep 2020 21:06:45
	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970' User entered '98.5'	System	13 Sep 2020 21:06:45
	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970'	System	13 Sep 2020 21:06:45
User entered 'No (N)'	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a98981a6-4486-4182-b63d-0edc3edd1970' User entered '13 Sep 2020 14:06'	System	13 Sep 2020 21:06:45
	System	13 Sep 2020 21:06:45

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:02:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37' User entered 'Yes (Y)'	System	15 Sep 2020 18:03:10
	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37' User entered '98.2'	System	15 Sep 2020 18:03:10
	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered 'No (N)'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '74081002-eff3-452b-a0ee-0df27c18ef37'	System	15 Sep 2020 18:03:10
User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:10

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:51', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'None (1)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T11:59:56', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d' User entered 'No (N)'	System	08 Sep 2020 19:00:11
	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'No (N)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d'	System	08 Sep 2020 19:00:11
User entered 'None (1)'	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'f05de605-353d-4364-a9c5-5f42f40f7c0d' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:00:11
	System	08 Sep 2020 19:00:11

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e' User entered 'No (N)'	System	09 Sep 2020 00:51:25
	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e' User entered 'No (N)'	System	09 Sep 2020 00:51:25
	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e'	System	09 Sep 2020 00:51:25
User entered 'None (1)'	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '52d22e7f-6d3d-44e8-b6d8-fd833c1bf46e' User entered '08 Sep 2020 17:51'	System	09 Sep 2020 00:51:25
	System	09 Sep 2020 00:51:25

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e'	System	09 Sep 2020 23:26:52
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:25:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered 'Yes (Y)'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered '1'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:40', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered 'No (N)'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered 'None (1)'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:48', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e95cf29-2030-40ad-a7ed-8b1509bd5d5e' User entered '09 Sep 2020 16:26'	System	09 Sep 2020 23:26:52
	System	09 Sep 2020 23:26:52

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a' User entered 'No (N)'	System	11 Sep 2020 00:42:06
	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a'	System	11 Sep 2020 00:42:06
User entered 'No (N)'	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:41:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a' User entered 'None (1)'	System	11 Sep 2020 00:42:06
	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a6e87769-b3a7-44cd-ad46-af774c98ef9a' User entered '10 Sep 2020 17:42'	System	11 Sep 2020 00:42:06
	System	11 Sep 2020 00:42:06

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:00:57', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e' User entered 'None (1)'	System	12 Sep 2020 01:01:16
	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e' User entered 'No (N)'	System	12 Sep 2020 01:01:16
	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e' User entered 'No (N)'	System	12 Sep 2020 01:01:16
	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e' User entered 'None (1)'	System	12 Sep 2020 01:01:16
	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '974794f0-f562-4506-83ab-06660e3a015e' User entered '11 Sep 2020 18:01'	System	12 Sep 2020 01:01:16
	System	12 Sep 2020 01:01:16

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:16:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'None (1)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec' User entered 'No (N)'	System	13 Sep 2020 03:17:14
	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec' User entered 'No (N)'	System	13 Sep 2020 03:17:14
	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered 'None (1)'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'ac3bcf8a-ee11-4c63-92f1-31f82340f3ec'	System	13 Sep 2020 03:17:14
User entered '12 Sep 2020 20:17'	System	13 Sep 2020 03:17:14

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:36', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8'	System	13 Sep 2020 21:07:03
User entered 'None (1)'	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8' User entered 'No (N)'	System	13 Sep 2020 21:07:03
	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8' User entered 'No (N)'	System	13 Sep 2020 21:07:03
	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8' User entered 'None (1)'	System	13 Sep 2020 21:07:03
	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:06:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c0fa5c6c-ba8a-4390-9b27-c953d3482ad8' User entered '13 Sep 2020 14:06'	System	13 Sep 2020 21:07:03
	System	13 Sep 2020 21:07:03

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef'	System	15 Sep 2020 18:03:37
User entered 'None (1)'	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef' User entered 'No (N)'	System	15 Sep 2020 18:03:37
	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:27', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef' User entered 'No (N)'	System	15 Sep 2020 18:03:37
	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef' User entered 'None (1)'	System	15 Sep 2020 18:03:37
	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc1e3cb4-cc82-4bfc-b680-6c5d1c27bbef' User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:37
	System	15 Sep 2020 18:03:37

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:25', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'None (0)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered 'No (N)'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T12:00:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '12a0b870-b409-4de9-90aa-c08a1522fa74' User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:00:40
	System	08 Sep 2020 19:00:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 11:42'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'None (0)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered 'No (N)'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-08T17:51:48', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'dde5e35f-66eb-43ea-a5e2-706462506ae0' User entered '08 Sep 2020 17:51'	System	09 Sep 2020 00:51:49
	System	09 Sep 2020 00:51:49

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '08 Sep 2020 15:07'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 2'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:26:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'None (0)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered 'No (N)'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-09T16:27:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71eaf7c2-8b57-45ec-8d0c-0b16bcea11e7' User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:27:47
	System	09 Sep 2020 23:27:47

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 3'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:12', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'None (0)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered 'No (N)'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-10T17:42:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1c6599df-367a-4f42-a284-3175ad1a7628' User entered '10 Sep 2020 17:42'	System	11 Sep 2020 00:42:37
	System	11 Sep 2020 00:42:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 4'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:19', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'None (0)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered 'No (N)'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-11T18:01:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6ad8f966-39b7-4c9f-ba97-f16b945fc1df' User entered '11 Sep 2020 18:01'	System	12 Sep 2020 01:01:37
	System	12 Sep 2020 01:01:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 5'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:25', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:30', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'None (0)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered 'No (N)'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-12T20:17:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e04ee3c8-57f1-4d06-ba32-648fa0949cc4' User entered '12 Sep 2020 20:17'	System	13 Sep 2020 03:17:37
	System	13 Sep 2020 03:17:37

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 6'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'None (0)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:21', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered 'No (N)'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-13T14:07:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'bc0a136e-3b12-43d4-a884-5f65ae6543fb' User entered '13 Sep 2020 14:07'	System	13 Sep 2020 21:07:27
	System	13 Sep 2020 21:07:27

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	08 Sep 2020 18:32:40
User entered 'Day 7'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:39', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:41', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:43', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:47', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'None (0)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:50', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered 'No (N)'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-09-15T11:03:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5f7a931e-36a6-4b3c-a447-0a45b9039919' User entered '15 Sep 2020 11:03'	System	15 Sep 2020 18:03:53
	System	15 Sep 2020 18:03:53

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:32:40

US3772037

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:46:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:32:40

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:49
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:49
User entered '15 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:49
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:49
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 23:20:03

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:49:54
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 23:20:07

US3772037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	15 Sep 2020 23:20:07

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:01
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:01
User entered '22 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:01
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:01
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:42:41

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:06
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:42:45

US3772037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	22 Sep 2020 22:42:45

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:12
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:12
User entered '29 Sep 2020'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:12
User entered 'Contact Made (CONTACT MADE)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:12
User entered empty.	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:33

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:17
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Sep 2020 19:20:47

US3772037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	29 Sep 2020 19:20:47

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:24
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:24
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:24
User entered 'Clinic (Clinic)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'VISIT3'	System	12 Oct 2020 16:12:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '08:40'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '12 Oct 2020 08:40'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '36.3' C	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered 'Oral (Oral)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '64'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'bpm'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '17'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'breaths/min'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '121'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:30
User entered '65'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'mmHg'	System	12 Oct 2020 16:13:19

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40

US3772037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:35
User entered 'No (N)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:35
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:13:26

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:39
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:39
User entered '12 Oct 2020'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:39
User entered '09:00'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered '12 Oct 2020 09:00'	System	12 Oct 2020 16:14:30

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:36:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:43
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	12 Oct 2020 16:14:35

US3772037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	12 Oct 2020 16:14:35

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 64'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you had 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8' User entered 'No (N)'	System	11 Oct 2020 14:42:58
	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:45', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8'	System	11 Oct 2020 14:42:58
User entered 'No (N)'	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-11T07:42:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fd33b6f6-4354-483c-81d8-d2228cac43f8' User entered '11 Oct 2020 07:42:55'	System	11 Oct 2020 14:42:58
	System	11 Oct 2020 14:42:58

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 71'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you had 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:10', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e' User entered 'No (N)'	System	18 Oct 2020 14:46:28
	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e' User entered 'No (N)'	System	18 Oct 2020 14:46:28
	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-18T07:46:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9e39e30b-ac00-4ce6-8986-3c52f2c4a78e' User entered '18 Oct 2020 07:46:24'	System	18 Oct 2020 14:46:28
	System	18 Oct 2020 14:46:28

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 78'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you had 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered 'No (N)'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:38', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered 'No (N)'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-10-25T14:24:44', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16e434f5-1be8-4b0b-9331-bb2ead9087f1' User entered '25 Oct 2020 14:24:44'	System	25 Oct 2020 21:24:47
	System	25 Oct 2020 21:24:47

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 92'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:46:46', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:46:55', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Please contact your study clinic 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:47:03', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:47:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '1'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '1'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '0'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:04', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered '0'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Please contact your study clinic 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'Yes (Y)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Please contact your study clinic 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029'	System	08 Nov 2020 10:48:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-08T02:48:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '589dd04c-26a5-46d6-937a-fa9c4f2b3029' User entered '08 Nov 2020 02:48:22'	System	08 Nov 2020 10:48:33
	System	08 Nov 2020 10:48:33

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered 'Day 99'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you had 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86'	System	15 Nov 2020 18:28:11
User entered 'No (N)'	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:05', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86'	System	15 Nov 2020 18:28:11
User entered 'No (N)'	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-15T10:28:08', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '3b4becf6-294f-470b-a99e-83a45ee1ae86' User entered '15 Nov 2020 10:28:08'	System	15 Nov 2020 18:28:11
	System	15 Nov 2020 18:28:11

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 17:21:08

US3772037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:12:18
Data entry locked.	System	11 Aug 2020 17:21:08
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 17:21:08

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:15', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b' User entered 'No (N)'	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b'	System	22 Nov 2020 10:58:38
User entered 'No (N)'	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-22T02:58:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '16da268c-4a5f-4823-83b8-05ab35b8db3b' User entered '22 Nov 2020 02:58:33'	System	22 Nov 2020 10:58:38
	System	22 Nov 2020 10:58:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-26T16:57:02', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc33fae4-714b-4586-861b-ab73fd04cddd' User entered 'No (N)'	System	27 Nov 2020 00:57:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-26T16:57:06', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc33fae4-714b-4586-861b-ab73fd04cddd' User entered 'No (N)'	System	27 Nov 2020 00:57:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-11-26T16:57:09', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'fc33fae4-714b-4586-861b-ab73fd04cddd' User entered '26 Nov 2020 16:57:09'	System	27 Nov 2020 00:57:12
	System	27 Nov 2020 00:57:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-03T22:04:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1dca240a-2e30-4294-8fa0-252fa5e3684e' User entered 'No (N)'	System	04 Dec 2020 06:04:27
	System	04 Dec 2020 06:04:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-03T22:04:20', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1dca240a-2e30-4294-8fa0-252fa5e3684e' User entered 'No (N)'	System	04 Dec 2020 06:04:27
	System	04 Dec 2020 06:04:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-03T22:04:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1dca240a-2e30-4294-8fa0-252fa5e3684e' User entered '03 Dec 2020 22:04:24'	System	04 Dec 2020 06:04:27
	System	04 Dec 2020 06:04:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-10T04:59:25', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '88be9ca6-5c9d-443a-b687-bc06dd6f444f' User entered 'No (N)'	System	10 Dec 2020 13:00:31
	System	10 Dec 2020 13:00:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-10T04:59:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '88be9ca6-5c9d-443a-b687-bc06dd6f444f' User entered 'No (N)'	System	10 Dec 2020 13:00:31
	System	10 Dec 2020 13:00:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-10T05:00:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '88be9ca6-5c9d-443a-b687-bc06dd6f444f' User entered '10 Dec 2020 05:00:28'	System	10 Dec 2020 13:00:31
	System	10 Dec 2020 13:00:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-17T00:03:01', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5e6a704e-35ef-4c0e-ad01-fff4b9cff6d0'	System	17 Dec 2020 08:03:16
User entered 'No (N)'	System	17 Dec 2020 08:03:16

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-17T00:03:07', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5e6a704e-35ef-4c0e-ad01-fff4b9cff6d0'	System	17 Dec 2020 08:03:16
User entered 'No (N)'	System	17 Dec 2020 08:03:16

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-17T00:03:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5e6a704e-35ef-4c0e-ad01-fff4b9cff6d0' User entered '17 Dec 2020 00:03:14'	System	17 Dec 2020 08:03:16
	System	17 Dec 2020 08:03:16

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-24T06:54:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a9aab755-8ef2-4c31-b255-0821ef7d9bef' User entered 'No (N)'	System	24 Dec 2020 14:54:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-24T06:54:23', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a9aab755-8ef2-4c31-b255-0821ef7d9bef'	System	24 Dec 2020 14:54:31
User entered 'No (N)'	System	24 Dec 2020 14:54:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-24T06:54:26', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'a9aab755-8ef2-4c31-b255-0821ef7d9bef' User entered '24 Dec 2020 06:54:26'	System	24 Dec 2020 14:54:31

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-31T07:32:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71060915-6b87-47f1-a379-2aa1914fa4b5' User entered 'No (N)'	System	31 Dec 2020 15:32:40
	System	31 Dec 2020 15:32:40

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-31T07:32:32', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71060915-6b87-47f1-a379-2aa1914fa4b5' User entered 'No (N)'	System	31 Dec 2020 15:32:40
	System	31 Dec 2020 15:32:40

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2020-12-31T07:32:35', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '71060915-6b87-47f1-a379-2aa1914fa4b5' User entered '31 Dec 2020 07:32:35'	System	31 Dec 2020 15:32:40
	System	31 Dec 2020 15:32:40

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-08T07:00:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e59c25f8-7f59-4cce-897e-38654595d8d7'	System	08 Jan 2021 15:00:19
User entered 'No (N)'	System	08 Jan 2021 15:00:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-08T07:00:14', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e59c25f8-7f59-4cce-897e-38654595d8d7'	System	08 Jan 2021 15:00:19
User entered 'No (N)'	System	08 Jan 2021 15:00:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-08T07:00:17', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e59c25f8-7f59-4cce-897e-38654595d8d7' User entered '08 Jan 2021 07:00:17'	System	08 Jan 2021 15:00:19
	System	08 Jan 2021 15:00:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-14T07:02:11', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1046970a-639b-4450-8a4f-01693d69ca53'	System	14 Jan 2021 15:02:19
User entered 'No (N)'	System	14 Jan 2021 15:02:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-14T07:02:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1046970a-639b-4450-8a4f-01693d69ca53'	System	14 Jan 2021 15:02:19
User entered 'No (N)'	System	14 Jan 2021 15:02:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-14T07:02:16', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '1046970a-639b-4450-8a4f-01693d69ca53' User entered '14 Jan 2021 07:02:16'	System	14 Jan 2021 15:02:19

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-23T08:29:22', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e6691239-bd5d-4d95-b3d9-6e9f470b1c42'	System	23 Jan 2021 16:29:38
User entered 'No (N)'	System	23 Jan 2021 16:29:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-23T08:29:29', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e6691239-bd5d-4d95-b3d9-6e9f470b1c42'	System	23 Jan 2021 16:29:38
User entered 'No (N)'	System	23 Jan 2021 16:29:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-23T08:29:33', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'e6691239-bd5d-4d95-b3d9-6e9f470b1c42'	System	23 Jan 2021 16:29:38
User entered '23 Jan 2021 08:29:33'	System	23 Jan 2021 16:29:38

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-28T10:21:13', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '51d81964-1167-4fc2-8576-3e7e8949ad16' User entered 'No (N)'	System	28 Jan 2021 18:21:33
	System	28 Jan 2021 18:21:33

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-28T10:21:24', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '51d81964-1167-4fc2-8576-3e7e8949ad16' User entered 'No (N)'	System	28 Jan 2021 18:21:33
	System	28 Jan 2021 18:21:33

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-01-28T10:21:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '51d81964-1167-4fc2-8576-3e7e8949ad16' User entered '28 Jan 2021 10:21:28'	System	28 Jan 2021 18:21:33

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-04T14:04:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9da1d27f-d6f2-427c-b946-4044699ade03' User entered 'No (N)'	System	04 Feb 2021 22:04:39
	System	04 Feb 2021 22:04:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-04T14:04:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9da1d27f-d6f2-427c-b946-4044699ade03' User entered 'No (N)'	System	04 Feb 2021 22:04:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-04T14:04:37', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9da1d27f-d6f2-427c-b946-4044699ade03' User entered '04 Feb 2021 14:04:37'	System	04 Feb 2021 22:04:39
	System	04 Feb 2021 22:04:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-13T13:05:28', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9b3e55ff-e6a5-4432-a5d3-528478778a6f' User entered 'No (N)'	System	13 Feb 2021 21:05:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-13T13:05:31', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9b3e55ff-e6a5-4432-a5d3-528478778a6f' User entered 'No (N)'	System	13 Feb 2021 21:05:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-13T13:05:34', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '9b3e55ff-e6a5-4432-a5d3-528478778a6f' User entered '13 Feb 2021 13:05:34'	System	13 Feb 2021 21:05:39
	System	13 Feb 2021 21:05:39

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-18T06:38:49', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8e715b60-0b5e-4b1a-954b-35613dd975f2'	System	18 Feb 2021 14:39:00
User entered 'No (N)'	System	18 Feb 2021 14:39:00

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-18T06:38:52', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8e715b60-0b5e-4b1a-954b-35613dd975f2'	System	18 Feb 2021 14:39:00
User entered 'No (N)'	System	18 Feb 2021 14:39:00

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-18T06:38:58', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '8e715b60-0b5e-4b1a-954b-35613dd975f2' User entered '18 Feb 2021 06:38:58'	System	18 Feb 2021 14:39:00
	System	18 Feb 2021 14:39:00

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:10-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4edf3e6b-492a-4dc6-bc0e-fa1ffdec4da0'	System	28 Feb 2021 17:10:24
User entered 'No (N)'	System	28 Feb 2021 17:10:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:13-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4edf3e6b-492a-4dc6-bc0e-fa1ffdec4da0'	System	28 Feb 2021 17:10:24
User entered 'No (N)'	System	28 Feb 2021 17:10:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:16-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4edf3e6b-492a-4dc6-bc0e-fa1ffdec4da0'	System	28 Feb 2021 17:10:24
User entered '28 Feb 2021 09:04:16'	System	28 Feb 2021 17:10:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-04T00:37:38-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6360d2aa-5f14-4798-9866-83d9116e0def' User entered 'No (N)'	System	04 Mar 2021 08:37:55
	System	04 Mar 2021 08:37:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-04T00:37:44-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6360d2aa-5f14-4798-9866-83d9116e0def'	System	04 Mar 2021 08:37:55
User entered 'No (N)'	System	04 Mar 2021 08:37:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-04T00:37:51-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '6360d2aa-5f14-4798-9866-83d9116e0def' User entered '04 Mar 2021 00:37:51'	System	04 Mar 2021 08:37:55
	System	04 Mar 2021 08:37:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-11T00:02:15-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0e42203e-7035-484d-8bf8-3fd6660e03c6' User entered 'No (N)'	System	11 Mar 2021 08:02:24
	System	11 Mar 2021 08:02:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-11T00:02:18-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0e42203e-7035-484d-8bf8-3fd6660e03c6'	System	11 Mar 2021 08:02:24
User entered 'No (N)'	System	11 Mar 2021 08:02:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-11T00:02:21-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0e42203e-7035-484d-8bf8-3fd6660e03c6' User entered '11 Mar 2021 00:02:21'	System	11 Mar 2021 08:02:24
	System	11 Mar 2021 08:02:24

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-18T06:42:59-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0d6eac43-cffb-47bb-a357-fcfa1b609b1f' User entered 'No (N)'	System	18 Mar 2021 13:43:12
	System	18 Mar 2021 13:43:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-18T06:43:05-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0d6eac43-cffb-47bb-a357-fcfa1b609b1f' User entered 'No (N)'	System	18 Mar 2021 13:43:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-18T06:43:08-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0d6eac43-cffb-47bb-a357-fcfa1b609b1f' User entered '18 Mar 2021 06:43:08'	System	18 Mar 2021 13:43:12
	System	18 Mar 2021 13:43:12

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-25T15:32:06-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2a747b44-f6c5-4a7e-b4a5-cd8500e5982d' User entered 'No (N)'	System	25 Mar 2021 22:34:23
	System	25 Mar 2021 22:34:23

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-25T15:32:09-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2a747b44-f6c5-4a7e-b4a5-cd8500e5982d' User entered 'No (N)'	System	25 Mar 2021 22:34:23

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-03-25T15:32:13-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2a747b44-f6c5-4a7e-b4a5-cd8500e5982d' User entered '25 Mar 2021 15:32:13'	System	25 Mar 2021 22:34:23
	System	25 Mar 2021 22:34:23

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-01T04:58:37-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4659aec6-04d0-4481-be24-1dfd48ce83ec' User entered 'No (N)'	System	01 Apr 2021 11:58:46
	System	01 Apr 2021 11:58:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-01T04:58:40-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4659aec6-04d0-4481-be24-1dfd48ce83ec' User entered 'No (N)'	System	01 Apr 2021 11:58:46
	System	01 Apr 2021 11:58:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-01T04:58:43-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '4659aec6-04d0-4481-be24-1dfd48ce83ec' User entered '01 Apr 2021 04:58:43'	System	01 Apr 2021 11:58:46
	System	01 Apr 2021 11:58:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-10T15:55:45-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2b241a7d-9b3f-4498-9721-96626f757a42'	System	10 Apr 2021 22:55:55
User entered 'No (N)'	System	10 Apr 2021 22:55:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-10T15:55:50-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2b241a7d-9b3f-4498-9721-96626f757a42'	System	10 Apr 2021 22:55:55
User entered 'No (N)'	System	10 Apr 2021 22:55:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-10T15:55:52-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '2b241a7d-9b3f-4498-9721-96626f757a42'	System	10 Apr 2021 22:55:55
User entered '10 Apr 2021 15:55:52'	System	10 Apr 2021 22:55:55

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-15T09:18:37-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd3f0f719-bd98-4d25-b6e5-84d7fbce5e65'	System	15 Apr 2021 16:20:27
User entered 'No (N)'	System	15 Apr 2021 16:20:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-15T09:18:39-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd3f0f719-bd98-4d25-b6e5-84d7fbce5e65'	System	15 Apr 2021 16:20:27
User entered 'No (N)'	System	15 Apr 2021 16:20:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-15T09:18:41-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'd3f0f719-bd98-4d25-b6e5-84d7fbce5e65'	System	15 Apr 2021 16:20:27
User entered '15 Apr 2021 09:18:41'	System	15 Apr 2021 16:20:27

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-22T04:17:18-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5a0ae783-8b73-4aa7-a410-d35ea7075eeb' User entered 'No (N)'	System	22 Apr 2021 11:17:29
	System	22 Apr 2021 11:17:29

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-22T04:17:21-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5a0ae783-8b73-4aa7-a410-d35ea7075eeb' User entered 'No (N)'	System	22 Apr 2021 11:17:29
	System	22 Apr 2021 11:17:29

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-22T04:17:24-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '5a0ae783-8b73-4aa7-a410-d35ea7075eeb' User entered '22 Apr 2021 04:17:24'	System	22 Apr 2021 11:17:29
	System	22 Apr 2021 11:17:29

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you had 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-29T12:47:14-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c90b7c79-00f2-40f1-98eb-8f2736ca1140'	System	29 Apr 2021 19:47:25
User entered 'No (N)'	System	29 Apr 2021 19:47:25

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Have you been exposed to someone with known SARS-CoV-2 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 (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-29T12:47:17-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c90b7c79-00f2-40f1-98eb-8f2736ca1140'	System	29 Apr 2021 19:47:25
User entered 'No (N)'	System	29 Apr 2021 19:47:25

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-04-29T12:47:19-07:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: 'c90b7c79-00f2-40f1-98eb-8f2736ca1140'	System	29 Apr 2021 19:47:25
User entered '29 Apr 2021 12:47:19'	System	29 Apr 2021 19:47:25

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:49:46

US3772037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:49:46
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:49:46

US3772037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:46:50

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)	30 Apr 2021 19:14:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:21-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0aaa0750-2db9-4413-9f92-3b11c94a704f' User entered 'Yes (Y)'	System	28 Feb 2021 17:11:02
	System	28 Feb 2021 17:11:02

US3772037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:46:50

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:14:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:37-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0aaa0750-2db9-4413-9f92-3b11c94a704f' User entered 'Yes (Y)'	System	28 Feb 2021 17:11:02
	System	28 Feb 2021 17:11:02

US3772037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:46:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:14:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (814FFC94-BFE6-489F-9F28-35F78264472E)', Time: '2021-02-28T09:04:41-08:00', User OID: 'PatientReportedOutcome (US3772037)', ODM File OID: '0aaa0750-2db9-4413-9f92-3b11c94a704f' User entered '28 Feb 2021 09:04:41'	System	28 Feb 2021 17:11:02
	System	28 Feb 2021 17:11:02

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:50
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:50
User entered '04 Nov 2020'	Sarah Sandberg (b) (4) (b) (4)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:50
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:50
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	19 Nov 2020 17:31:45

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:50:56
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	19 Nov 2020 17:31:53

US3772037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:31:40
User entered 'I'	System	19 Nov 2020 17:31:53

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:05
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	07 Dec 2020 17:37:59

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:05
User entered '7 Dec 2020'	Matthew Pohlmeier (b) (4)	07 Dec 2020 17:37:59

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:05
User entered 'Contact Made (CONTACT MADE)'	Matthew Pohlmeier (b) (4)	07 Dec 2020 17:37:59

US3772037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:05
User entered empty.	Matthew Pohlmeier (b) (4)	07 Dec 2020 17:37:59

US3772037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:11
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	07 Dec 2020 17:38:04

US3772037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered 'I'	System	07 Dec 2020 17:38:04

US3772037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:38
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Jan 2021 16:21:08

US3772037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:38
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '06 Jan 2021'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Jan 2021 16:21:08

US3772037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:38
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Jan 2021 16:21:08

US3772037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:38
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Jan 2021 16:21:08

US3772037

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:44
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Jan 2021 16:21:13

US3772037

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered 'I'	System	06 Jan 2021 16:21:13

US3772037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:50
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:22:19

US3772037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:50
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '2 Feb 2021'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:22:19

US3772037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:50
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:22:19

US3772037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:50
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:22:19

US3772037

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:37:54
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:22:24

US3772037

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:21:58
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered 'I'	System	02 Feb 2021 22:22:24

US3772037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:33
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:03:27

US3772037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:33
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered '17 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:03:27

US3772037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[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 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:33
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'Clinic (Clinic)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:03:27

US3772037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered 'VISIT4'	System	17 Mar 2021 21:03:27

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered empty.	System	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered empty.	System	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered empty.	System	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered empty.	System	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:40
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:10
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered empty.	System	01 Apr 2021 21:24:18

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28

US3772037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28

US3772037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:47
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'No (N)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:03:35

US3772037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:47
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:03:35

US3772037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:57
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:04:04

US3772037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:57
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered '17 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:04:04

US3772037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:29:57
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered '13:50'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:04:04

US3772037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
User entered '17 Mar 2021 13:50'	System	17 Mar 2021 21:04:04

US3772037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:30:02
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 21:04:11

US3772037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:12
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:28
User entered 'I'	System	17 Mar 2021 21:04:11

US3772037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Apr 2021 19:18:48
	(b) (4)	

US3772037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
	(b) (4)	
User entered '05 Apr 2021'	Sarah Sandberg (b) (4)	05 Apr 2021 19:18:48
	(b) (4)	

US3772037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Apr 2021 19:18:48

US3772037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	05 Apr 2021 19:18:48
	(b) (4)	

US3772037

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Apr 2021 19:18:52
	(b) (4)	

US3772037

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:18:52

US3772037

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:14:58

US3772037

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:38
User entered '3 May 2021'	(b) (4), (b) (6)	03 May 2021 18:14:58

US3772037

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:14:58

US3772037

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:38
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:14:58

US3772037

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:15:07

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Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:15:07

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:54
User entered '9 Nov 2020' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	03 Dec 2020 22:06:10
User entered '6 Nov 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 19:58:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:54
User entered '09:53' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 22:06:10
User entered '04:25'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 19:58:42

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:38
User entered '9 Nov 2020 09:53'	System	03 Dec 2020 22:06:10
User entered '6 Nov 2020 04:25'	System	03 Dec 2020 19:58:42

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:54
User entered 'Safety Call (Safety Call)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 19:58:42

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:38
User closed query 'Per CDM: Has the subject reported symptoms of SARS-COV-2? is Yes, however symptoms are not recorded on symptom log. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 12:41:04
Query 'Per CDM: Has the subject reported symptoms of SARS-COV-2? is Yes, however symptoms are not recorded on symptom log. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'Symptom log was inactivated as its not needed since this was only created to document another swab taken' (Site from DM).	Emily Crews (b) (4) (b) (4)	21 Apr 2021 15:16:27
User opened query 'Per CDM: Has the subject reported symptoms of SARS-COV-2? is Yes, however symptoms are not recorded on symptom log. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:23:15
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:51:54
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 19:58:42

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:09:42
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 09NOV2020 is recorded under Covid-19 Assessment visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 08:14:10
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 09NOV2020 is recorded under Covid-19 Assessment visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'This is not an actual visit this information was requested to be entered by our CRA to correspond with the SAE for COVID-19 Infection. No swab was taken from our site on this date subject was seen for illness visit 13 Nov 2020 ' (Site from DM).	Emily Crews (b) (4) (b) (4)	29 Dec 2020 00:27:15
DataPoint Un-verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:19
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 09NOV2020 is recorded under Covid-19 Assessment visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:48:33
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered '9 Nov 2020' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 22:06:34
User entered '5 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 11:35:39
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Yes test results per both lab records (CLIA certified Lab 24) and subject report. AE log for Covid 19 infection is added. ' (Site from System).	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:22:11
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 02:25:34
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Dec 2020 20:03:01
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:11:50
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'This is for an outside test conducted prior to Day 1 Illness visit' (Site from DM).	Emily Crews (b) (4) (b) (4)	12 Mar 2021 19:33:30
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:28:10
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 06NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:55:49
' (Site from DM).		
Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 06NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:17:36
' answered with 'This is that date of collection for the swab taken at an outside lab' (Site from DM).		

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 06NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	29 Jan 2021 07:27:55
	(b) (4), (b) (6) (b) (4)	04 Dec 2020 02:25:34
User entered '6 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered 'Nasal Swab (Nasal Swab)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User entered 'LAB24 475 Knollocrest Drive. Redding, CA 96002'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 02:25:34
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Dec 2020 20:29:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:29:41
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Dec 2020 20:03:01
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:03:01

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:55
User entered 'I'	System	03 Dec 2020 20:03:01

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM: It appears that 'Did the subject have Respiratory Rates ≥ 30 per Minute?' is recorded as No yet data is present as 16/minute yet Illness Visit has 15/Minute. Please review and reconcile ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:17:40
Query 'Per CDM: It appears that 'Did the subject have Respiratory Rates ≥ 30 per Minute?' is recorded as No yet data is present as 16/minute yet Illness Visit has 15/Minute. Please review and reconcile ' answered with 'Data has been removed' (Site from DM).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 22:46:53
User opened query 'Per CDM: It appears that 'Did the subject have Respiratory Rates ≥ 30 per Minute?' is recorded as No yet data is present as 16/minute yet Illness Visit has 15/Minute. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:25:27
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	25 Jan 2021 22:46:42
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	25 Jan 2021 22:46:42
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered '16'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM: It appears that 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' recorded as Yes with dates of 07NOV2020 - 12NOV2020 at 88% yet per Symptom Log, there are 2 records (Day 6 and Day 7) at 91 % and 93% respectively. Please review and reconcile ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:17:50
Query 'Per CDM: It appears that 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' recorded as Yes with dates of 07NOV2020 - 12NOV2020 at 88% yet per Symptom Log, there are 2 records (Day 6 and Day 7) at 91 % and 93% respectively. Please review and reconcile ' answered with 'please advise how to capture this data correctly if they experienced multiple different O2 levels under 93' (Site from DM).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 22:47:20
User opened query 'Per CDM: It appears that 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' recorded as Yes with dates of 07NOV2020 - 12NOV2020 at 88% yet per Symptom Log, there are 2 records (Day 6 and Day 7) at 91 % and 93% respectively. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:28:44
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User closed query 'Per CDM: re-query, the end date and the Oxygen saturation % do not match the Symptom log. The Symptom log has a lowest O2 Saturation of 91% on 18Nov2020. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 15:33:25
Query 'Per CDM: re-query, the end date and the Oxygen saturation % do not match the Symptom log. The Symptom log has a lowest O2 Saturation of 91% on 18Nov2020. Please review and clarify.' answered with 'this date is reported due to subject being in hospital during the time of their COVID-19 Illness.' (Site from DM).	Emily Crews (b) (4) (b) (4)	23 Apr 2021 21:12:46
User opened query 'Per CDM: re-query, the end date and the Oxygen saturation % do not match the Symptom log. The Symptom log has a lowest O2 Saturation of 91% on 18Nov2020. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:06:17
User closed query 'Per CDM: Per the symptom log, the start and stop date appear to be 18Nov2020 to 19Nov2020 with the lowest O2 level being 91%. Please review and confirm and update the data, or clarify otherwise.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:12:47
Query 'Per CDM: Per the symptom log, the start and stop date appear to be 18Nov2020 to 19Nov2020 with the lowest O2 level being 91%. Please review and confirm and update the data, or clarify otherwise.' answered with 'This was documented per medical records received' (Site from DM).	Emily Crews (b) (4) (b) (4)	21 Apr 2021 15:18:23
User opened query 'Per CDM: Per the symptom log, the start and stop date appear to be 18Nov2020 to 19Nov2020 with the lowest O2 level being 91%. Please review and confirm and update the data, or clarify otherwise.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:43:23
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered '7 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered '12 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Folder: Covid-19 Assessment 09 Nov 2020

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered '88'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:26:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 20:26:43
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:26:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:22:50
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM: It appears that 'Did the subject have Respiratory failure?' is recorded as Yes and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is missing for 'If Yes to either Did subject require any of the following' for Covid-19 Assessment dated 09NOV2020. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 08:55:33
Query 'Per CDM: It appears that 'Did the subject have Respiratory failure?' is recorded as Yes and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is missing for 'If Yes to either Did subject require any of the following' for Covid-19 Assessment dated 09NOV2020. Please review and update accordingly. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Feb 2021 16:37:39
User opened query 'Per CDM: It appears that 'Did the subject have Respiratory failure?' is recorded as Yes and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is missing for 'If Yes to either Did subject require any of the following' for Covid-19 Assessment dated 09NOV2020. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 05:03:29
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Emily Crews (b) (4)	15 Feb 2021 16:37:30
	(b) (4)	
	Emily Crews (b) (4)	15 Feb 2021 16:35:37
	(b) (4)	
User entered '07 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4)	15 Feb 2021 16:35:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4)	03 Dec 2020 20:22:50
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:26:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 20:26:43
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:26:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:22:50
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4)	
	Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4)	03 Dec 2020 20:22:50
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Feb 2021 16:37:30
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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Audit	User	Time (GMT)
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User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Dec 2020 20:31:47
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Date of Assessment](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:18:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM: Please provide response for Radiographical Evidence.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:13:25
Query 'Per CDM: Please provide response for Radiographical Evidence.' answered with 'updated' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	10 Feb 2021 22:03:11
DataPoint Un-verified.	Sarah Sandberg (b) (4) (b) (4)	10 Feb 2021 22:03:06
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	10 Feb 2021 22:03:06
User opened query 'Per CDM: Please provide response for Radiographical Evidence.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:46:37
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:26:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 20:26:43
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:26:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:22:50
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:46:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:52:45
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	03 Dec 2020 20:22:50

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM: Please consider recording Covid-19 Infection on AE form to Covid - 19 or Symptomatic Covid-19. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:17:21
User closed query 'Per CDM: Please review ALL Covid Assessment Visits (09NOV2020 and 13NOV2020) and reconcile as there is only 1 event recorded as Covid-19 Infection with dates of 06NOV2020 - 20NOV2020. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:17:19
Query 'Per CDM: Please consider recording Covid-19 Infection on AE form to Covid - 19 or Symptomatic Covid-19. ' answered with 'Updated term' (Site from DM).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:22:05
Query 'Per CDM: Please review ALL Covid Assessment Visits (09NOV2020 and 13NOV2020) and reconcile as there is only 1 event recorded as Covid-19 Infection with dates of 06NOV2020 - 20NOV2020. ' answered with 'A second Covid contact was entered per CTM guidance ' (Site from DM).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:16:35
User opened query 'Per CDM: Please consider recording Covid-19 Infection on AE form to Covid - 19 or Symptomatic Covid-19. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:24:27
User opened query 'Per CDM: Please review ALL Covid Assessment Visits (09NOV2020 and 13NOV2020) and reconcile as there is only 1 event recorded as Covid-19 Infection with dates of 06NOV2020 - 20NOV2020. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:51:27
User entered '13 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:27
User entered '14:00'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:14
User entered '13 Nov 2020 14:00'	System	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:27
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:46:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:27
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:44:00

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 1 (Day 1)'	Ruba Zanaid (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Per ETRTR: Per eCRF completion guidelines "Day 1 is the start date of the symptoms begin as reported by subject". COVID-19 AE start date is 07Nov20. Please confirm if symptoms started on 13Nov20, if not, please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 09:07:49
Query 'Per ETRTR: Per eCRF completion guidelines "Day 1 is the start date of the symptoms begin as reported by subject". COVID-19 AE start date is 07Nov20. Please confirm if symptoms started on 13Nov20, if not, please update as appropriate. ' answered with 'updated ' (Site from CRA).	Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 23:58:28
User entered '07 Nov 2020' reason for change: Data Entry Error	Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 23:58:20
User opened query 'Per ETRTR: Per eCRF completion guidelines "Day 1 is the start date of the symptoms begin as reported by subject". COVID-19 AE start date is 07Nov20. Please confirm if symptoms started on 13Nov20, if not, please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 13:35:11
User entered '13 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '97'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '36.2' C	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:46:16

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Please consider if a new log line should be entered to capture data associated with Symptom date 08-13Nov2020.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:04
Query 'Please consider if a new log line should be entered to capture data associated with Symptom date 08-13Nov2020.' answered with 'Added' (Site from CRA).	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:24:56
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:24:35
User opened query 'Please consider if a new log line should be entered to capture data associated with Symptom date 08-13Nov2020.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 09:11:52
User entered 'Day 2 (Day 2)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:08:52
User entered '14 Nov 2020'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:08:57
User entered '94'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:08:59
User entered '98.1' F	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:06
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:03
User entered 'Mild (Mild)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:07
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:09
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:13
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:20
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:17
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:22
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:24
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:26
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:28
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:32
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:34
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:36
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:37
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 03:09:40
User entered 'None (None)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:50:57

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 4 (Day 4)'	(b) (4)	
	Sarah Sandberg (b) (4)	17 Nov 2020 00:32:37
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '16 Nov 2020'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '95'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '97.6' F	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:32:37

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 3 (Day 3)'	(b) (4)	
	Sarah Sandberg (b) (4)	17 Nov 2020 00:33:52
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '15 Nov 2020'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '94'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '98.1' F	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Sarah Sandberg (b) (4) (b) (4)	17 Nov 2020 00:33:52

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 5 (Day 5)'	(b) (4)	
	Emily Crews (b) (4)	17 Nov 2020 21:44:26
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '17 Nov 2020'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '94'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '36.5' C	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Emily Crews (b) (4) (b) (4)	17 Nov 2020 21:44:26

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 6 (Day 6)'	(b) (4)	
	Emily Crews (b) (4)	19 Nov 2020 00:26:28
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '18 Nov 2020'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:57
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:22:28
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '91'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '36.7' C	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Mild (Mild)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	19 Nov 2020 00:26:28

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 7 (Day 7)'	(b) (4)	
	Emily Crews (b) (4)	20 Nov 2020 00:34:49
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query ' Please update and correct , month' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 07:23:10
Query ' Please update and correct , month' answered with 'UPdated' (Site from CRA).	Emily Crews (b) (4)	29 Dec 2020 00:23:48
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	29 Dec 2020 00:23:44
User opened query ' Please update and correct , month' (Site from CRA).	(b) (4), (b) (6)	20 Dec 2020 03:07:45
User entered '19 Oct 2020'	Emily Crews (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '93'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '36.7' C	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	Emily Crews (b) (4) (b) (4)	20 Nov 2020 00:34:49

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:24:35
User entered 'Day 8 (Day 8)'	(b) (4)	
	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '20 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '0'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '94'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '98.1' F	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'None (None)'	(b) (4), (b) (6)	21 Nov 2020 00:27:03

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 2 (Day 2)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:22:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 19:22:00
User entered '08 Nov 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:22:00
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:21:32
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:52
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
User closed query 'Per CDM: As the assessment NOT DONE, please tick ASSESSMENT NOT DONE field and leave all the other data fields below blank per CCG. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:50:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:19
Query 'Per CDM: As the assessment NOT DONE, please tick ASSESSMENT NOT DONE field and leave all the other data fields below blank per CCG. ' answered with 'Removed all data points' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:10:19
DataPoint Un-verified.	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:09:32
User opened query 'Per CDM: As the assessment NOT DONE, please tick ASSESSMENT NOT DONE field and leave all the other data fields below blank per CCG. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:57:58
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:52
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered empty.	System	20 Apr 2021 16:09:32
User entered '%'	System	03 Feb 2021 19:23:52
User entered empty.	System	03 Feb 2021 19:21:32

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:52
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:52
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (9)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:09:32
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:09:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:25:48
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 3 (Day 3)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:22:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 19:22:00
User entered '09 Nov 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:22:00
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:21:32
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User closed query 'Per CDM: Please verify that Symptom Log Line 10 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:51:16
Query 'Per CDM: Please verify that Symptom Log Line 10 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Removed all data points' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:11:42
User opened query 'Per CDM: Please verify that Symptom Log Line 10 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:45:47
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:52
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:52
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered empty.	System	20 Apr 2021 16:11:17
User entered '%'	System	03 Feb 2021 19:23:52
User entered empty.	System	03 Feb 2021 19:21:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:52
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:11:17
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:11:17
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:28:19
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 4 (Day 4)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:22:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 19:22:39
User entered '10 Nov 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:22:39
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:21:42
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User closed query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:51:47
Query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Removed all data points' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:13:03
User opened query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:46:47
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:21
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered empty.	System	20 Apr 2021 16:12:47
User entered '%'	System	03 Feb 2021 19:29:09
User entered empty.	System	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:12:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:29:09
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 5 (Day 5)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:22:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 19:22:39
User entered '11 Nov 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:22:39
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:21:42
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User closed query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:52:18
Query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Removed all data points' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:15:06
User opened query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:48:02
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:21
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered empty.	System	20 Apr 2021 16:14:47
User entered '%'	System	03 Feb 2021 19:30:07
User entered empty.	System	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (12)

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:14:47
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:14:47
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 6 (Day 6)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42

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Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:22:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 19:22:39
User entered '12 Nov 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:22:39
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:21:42
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User closed query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:52:43
Query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Removed all data points' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:16:30
User opened query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:48:45
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:21
User entered '0'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered empty.	System	20 Apr 2021 16:16:08
User entered '%'	System	03 Feb 2021 19:30:55
User entered empty.	System	03 Feb 2021 19:21:42

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Form: Symptom Log (13)

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:16:08
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:16:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:30:55
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:21:42
	(b) (4)	

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Day 7 (Day 7)'	Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21

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Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '13 Nov 2020'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:21

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
User closed query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 12:58:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:14:19
Query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Updated data with contact documented in source' (Site from DM).	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:21:59
DataPoint Un-verified.	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:18:38
User entered '0' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	20 Apr 2021 16:18:38
User opened query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:49:26
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered '1'	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:23:21

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Form: Symptom Log (14)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered '97' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User entered '%'	System	03 Feb 2021 19:31:49
User entered empty.	System	03 Feb 2021 19:23:21

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered '36.2' C reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Form: Symptom Log (14)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:46:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:45:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:14:19
DataPoint Un-verified.	Emily Crews (b) (4)	20 Apr 2021 16:18:38
Signature has been broken.	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	20 Apr 2021 16:18:38
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	03 Feb 2021 19:31:49
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	03 Feb 2021 19:23:21
	(b) (4)	

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered '13 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:56
User closed query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	(b) (4), (b) (6)	05 Feb 2021 06:31:01
' (Site from DM).		
Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:18:41
' answered with 'Updated transcription error on collection date' (Site from DM).		
DataPoint Un-verified.	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:18:24
User entered '13 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:18:24
User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 11NOV2020 is recorded under Covid-19 Assessment Visit in EDC, however the sample is missing in PPD Central lab. Please confirm if the sample has been shipped and provide Accession number and Tracking details in the response. Thank you.	(b) (4), (b) (6)	29 Jan 2021 07:30:17
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered '11 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 13-Nov-2020, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Jamshid Saleh (b) (4)	20 Apr 2021 07:25:11 15 Apr 2021 19:45:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:44:24
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 13-Nov-2020, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Thank you.' answered with 'This COVID Diagnostic test was updated to reflect the central lab results.' (Site from DM). User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	Sarah Sandberg (b) (4) (b) (4)	06 Apr 2021 15:58:38 06 Apr 2021 15:58:05
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	06 Apr 2021 15:57:58
DataPoint Un-verified.	Sarah Sandberg (b) (4) (b) (4)	06 Apr 2021 15:57:58

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Signature has been broken.	Sarah Sandberg (b) (4)	06 Apr 2021 15:57:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	06 Apr 2021 15:57:58
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 13-Nov-2020, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:44:49
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:43:56
DataPoint Un-verified.	Emily Crews (b) (4)	29 Dec 2020 00:23:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	29 Dec 2020 00:23:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered 'No (N)'	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:44:30
DataPoint Un-verified.	Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
Signature has been broken.	(b) (4) Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
User entered empty; reason for change Data Entry Error	(b) (4) Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:56
DataPoint Un-verified.	Emily Crews (b) (4)	29 Dec 2020 00:23:17
User entered 'LAB24' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	29 Dec 2020 00:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:44:33
DataPoint Un-verified.	Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
Signature has been broken.	(b) (4) Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
User entered empty; reason for change Data Entry Error	(b) (4) Sarah Sandberg (b) (4)	06 Apr 2021 15:58:05
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:56
DataPoint Un-verified.	Emily Crews (b) (4)	29 Dec 2020 00:23:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	29 Dec 2020 00:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:40
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 00:27:51

US3772037

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:46:50

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:28
User entered '0'	System	21 Nov 2020 00:27:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:46:50

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:04:33
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:51:46
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	14 Nov 2020 19:43:14

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered '15 Nov 2020'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered '17 Nov 2020'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered '19 Nov 2020'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered empty.	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered empty.	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered empty.	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:46:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:46:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:33
User entered empty.	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:19

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:56
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:02
User closed query 'Please update saliva collection log as required.' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 17:34:03
Query 'Please update saliva collection log as required.' answered with 'saliva collection logupdated' (Site from CRA).	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:31
User opened query 'Please update saliva collection log as required.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 09:13:52
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:36:25
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'There is no ecrf to complete for swab on Illness Day 1. Blood sampling is documented' (Site from DM).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:39:30
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13NOV2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:38:35
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:56
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:02
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:56
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:02
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:56
User entered 'SICKD1'	System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '14:15'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User entered '13 Nov 2020 14:15'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered missing code ND - Not Done.	Emily Crews (b) (4)	13 Nov 2020 22:56:55
DataPoint set to visible.	(b) (4) System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered missing code ND - Not Done.	Emily Crews (b) (4)	13 Nov 2020 22:56:55
DataPoint set to visible.	(b) (4) System	13 Nov 2020 22:53:48

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '36.2' C	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered empty.	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '75'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User entered 'bpm'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '15'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User entered 'breaths/min'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '132'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User entered 'mmHg'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:08
User entered '70'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03
User entered 'mmHg'	System	13 Nov 2020 22:56:55

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03

US3772037

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:03

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:14
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:04

US3772037

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:14
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:04

US3772037

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:21
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 , 17NOV2020 and 19NOV2020 reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:51:15
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 , 17NOV2020 and 19NOV2020 reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'saliva collection updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:38:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 , 17NOV2020 and 19NOV2020 reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:11:59
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:13

US3772037

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:21
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	13 Nov 2020 22:57:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:29
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:06:43

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:29
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:06:43

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:29
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:06:43

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	22 Mar 2021 22:06:43

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:42
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 22:07:13

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:47
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:16

US3772037

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:47
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:16

US3772037

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:46:50

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:54
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:23

US3772037

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:46:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:45:54
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Mar 2021 22:07:23

US3772037

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

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:13
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:23

US3772037

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

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:13
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:23

US3772037

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

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[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 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:13
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:23

US3772037

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

Form: Visit Date

Generated On: 10 Jun 2021 09:46:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 20:11:23

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[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 12:31:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:22

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:52:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:22

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:39:40
User entered 'mRNA-1273 (mRNA-1273)'	System	
	Emily Crews (b) (4)	08 Jan 2021 22:08:57
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:39:40
User entered 'mRNA-1273 (mRNA-1273)'	Emily Crews (b) (4)	08 Jan 2021 22:08:57
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:18
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User entered empty.	System	08 Jan 2021 22:08:57

US3772037

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

Form: Unblinding

Generated On: 10 Jun 2021 09:46:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User entered empty.	System	08 Jan 2021 22:08:57

US3772037

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:24
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 08JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:53:50
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 08JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'Stored onsite' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Feb 2021 16:08:44
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 08JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:22:47
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:34

US3772037

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:24
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:34

US3772037

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:24
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '11:38'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:34

US3772037

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User entered '08 Jan 2021 11:38'	System	08 Jan 2021 20:11:34

US3772037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:46

US3772037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:46

US3772037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '11:40'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Jan 2021 20:11:46

US3772037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:50
User entered '08 Jan 2021 11:40'	System	08 Jan 2021 20:11:46

US3772037

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:46:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:14
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:54:07
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:04:26

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:42:10
User entered	System	10 Nov 2020 15:42:05
'USA-US107-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 15:42:05

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:21:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:21:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:42:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:42:54
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: Please provide a description for the event of acute hypoxic respiratory failure, specifically providing rationale for start date of 07Nov2020 considering that the symptom log for 07Nov2020 indicates O2 sat 97% and hospitalization did not occur until 08Nov2020, and details of hospital course that did not involve admission to ICU.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 16:59:14
Query 'PV Query: Please provide a description for the event of acute hypoxic respiratory failure, specifically providing rationale for start date of 07Nov2020 considering that the symptom log for 07Nov2020 indicates O2 sat 97% and hospitalization did not occur until 08Nov2020, and details of hospital course that did not involve admission to ICU.' answered with 'Updated start date of this SAE previous start date was associated with the COVID-19 Dx' (Site from Safety).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:19:40

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide a description for the event of acute hypoxic respiratory failure, specifically providing rationale for start date of 07Nov2020 considering that the symptom log for 07Nov2020 indicates O2 sat 97% and hospitalization did not occur until 08Nov2020, and details of hospital course that did not involve admission to ICU.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:48:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:57
Data point term sent to Coder	System	24 Nov 2020 18:01:56
Coding entries removed.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User entered 'Acute Hypoxic Respiratory Failure due to COVID-19 Infection' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:11:35
Data point term sent to Coder	System	09 Nov 2020 19:11:02
User entered 'COVID-19 Infection'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 16:19:01
User closed query 'PV Query: The start date of the event is 07 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 07 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	Emily Crews (b) (4)	25 Nov 2020 16:34:15
Query 'PV Query: The start date of the event is 07 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 07 Nov 2020 to the COVID-19 assessment symptom log in EDC.' answered with 'Updated SAE term' (Site from Safety).	(b) (4), (b) (6)	
User opened query 'PV Query: The start date of the event is 07 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 07 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	Emily Crews (b) (4)	24 Nov 2020 18:01:35
User entered '07 Nov 2020'	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:56:42
	Emily Crews (b) (4)	09 Nov 2020 19:10:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	24 Nov 2020 18:10:14
User entered 'No (N)' reason for change: Data Entry Error	System	24 Nov 2020 18:10:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Emily Crews (b) (4)	24 Nov 2020 18:10:14
User entered 'Yes (Y)'	(b) (4)	24 Nov 2020 18:01:14
	Emily Crews (b) (4)	09 Nov 2020 19:10:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: As the symptoms of COVID-19 remained ongoing through 18 Nov 2020 (per COVID-19 assessment log), please consider updating the event stop date to the date the subject no longer had symptoms.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:52:31
Query 'PV Query: As the symptoms of COVID-19 remained ongoing through 18 Nov 2020 (per COVID-19 assessment log), please consider updating the event stop date to the date the subject no longer had symptoms.' answered with 'SAE is acute hypoxic respiratory failure. This is the stop date for this term ' (Site from Safety).	Emily Crews (b) (4) (b) (4)	04 Dec 2020 22:35:24
User opened query 'PV Query: As the symptoms of COVID-19 remained ongoing through 18 Nov 2020 (per COVID-19 assessment log), please consider updating the event stop date to the date the subject no longer had symptoms.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 17:05:38
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:34:13
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:41
User entered '12 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:56:00
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:09:03
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'event is ongoing' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:08:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:09:31
	Emily Crews (b) (4)	09 Nov 2020 19:10:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:34:11
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'UPdated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:45
User entered 'Grade 4 (Grade 4)' reason for change:	Emily Crews (b) (4)	24 Nov 2020 18:01:14
Data Entry Error	(b) (4)	
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:56:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4)	
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 05:56:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	Emily Crews (b) (4)	24 Nov 2020 18:01:57
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still in the hospital there is not a discharge date available' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:28:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:28:33
User entered '1'	Emily Crews (b) (4)	09 Nov 2020 19:11:15
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:10:35
	Emily Crews (b) (4)	09 Nov 2020 19:10:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '08 Nov 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:59:11
Query 'Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'These record shave already been sent to Safety' (Site from Safety).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:21:18
User opened query 'Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:54:59
Query 'PV Query: Please request hospital discharge summary if not previously requested. Thank you.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:53:49
User opened query 'PV Query: Please request hospital discharge summary if not previously requested. Thank you.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:53:44
User entered '12 Nov 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	16 Nov 2020 19:04:08
User entered empty.	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Emily Crews (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Emily Crews (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:34:06
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:02:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:01:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:56:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:09:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Ongoing' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:12:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:10:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:38:25
Query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' answered with 'Site awaiting receipt of Positive Covid test. Records have been requested twice' (Site from Safety).	Emily Crews (b) (4) (b) (4)	08 Dec 2020 20:16:50
User opened query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 17:07:38
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:34:03
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:34:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Conmeds have been updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Site has not received the requested positive test results. The GCL test came back negative. Until we receive the positive test results it cannot be entered into EDC therefore the severity assessment will not be populated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	24 Nov 2020 18:05:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 18:56:13
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 18:55:45
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 16:08:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Nov 2020 16:08:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Awaiting receipt of medical records' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:17:10

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'Awaiting receipt of medical records for covid testing' (Site from Safety). User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Nov 2020 23:16:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:10:06
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:08:06
User entered 'Subject was contacted regarding safety report of Covid exposure and symptoms. The subject reported being tested for Covid on the same day they were Dx with Sinusitis (05 Nov 2020) and receiving a positive result on 07 Nov 2020. The subject was advised to go to the hospital if their oxygen saturation was below90. The Subject reported having an O2 saturation of 88 on 8th of November. Self referred to ER. The subject was admitted as an Inpatient on 08 Nov 2020. Medical records have been requested for COVID test RESULTS and hospital stay.'	Emily Crews (b) (4) (b) (4)	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 19:10:35

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 12:38:45
User entered 'USA-US107-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	09 Dec 2020 12:38:42

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 16:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 16:19:48
Data point term sent to Coder	System	25 Jan 2021 16:19:19
Coding entries removed.	Emily Crews (b) (4)	25 Jan 2021 16:18:36
User entered 'COVID 19' reason for change: Data Entry Error	Emily Crews (b) (4)	25 Jan 2021 16:18:36
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:21:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:21:40
Data point term sent to Coder	System	08 Dec 2020 22:19:18
User entered 'Covid 19 Infection'	Ruba Zanaid (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:28:55
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4)	23 Feb 2021 16:05:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	23 Feb 2021 16:05:47
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:15:10
User entered 'No (N)'	Ruba Zanaid (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '6 Nov 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '20 Nov 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: As subject received both doses of SD, please update action taken from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:12
Query 'PV Query: As subject received both doses of SD, please update action taken from none to not applicable.' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	29 Dec 2020 00:22:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	29 Dec 2020 00:22:40
User opened query 'PV Query: As subject received both doses of SD, please update action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:46:00
User entered 'None (NONE)'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:20:37
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:18:28
User entered '0' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:17:16
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:02:26
User entered '1'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '1' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	25 Jan 2021 16:17:16
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 22:18:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'PV Query: Please consider whether the symptoms leading to diagnosis of sinusitis on 05Dec2020 might be symptoms of COVID-19 and update event start date and symptom log if appropriate. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:00:08
Query 'PV Query: Please consider whether the symptoms leading to diagnosis of sinusitis on 05Dec2020 might be symptoms of COVID-19 and update event start date and symptom log if appropriate. ' answered with 'Subject was diagnosed with Sinusitis prior to diagnosis of COVID' (Site from Safety).	Emily Crews (b) (4) (b) (4)	25 Jan 2021 16:18:24
User opened query 'PV Query: Please consider whether the symptoms leading to diagnosis of sinusitis on 05Dec2020 might be symptoms of COVID-19 and update event start date and symptom log if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 18:52:00
User closed query 'PV Query: Please confirm date of COVID-19 test, which is reported as 06 NOV but case narrative reflects subject was tested on 05 NOV and received positive results on 07 NOV.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 17:28:18
User closed query 'PV Query: Please confirm date for Day 7 in the COVID-19 assessment log. Currently is reported as 19 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 17:28:06
User closed query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 17:27:58
Query 'PV Query: Please confirm date for Day 7 in the COVID-19 assessment log. Currently is reported as 19 Oct 2020.' answered with 'Day 7 date has been updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	29 Dec 2020 00:24:25
Query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' answered with 'COVID testing information has been updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	29 Dec 2020 00:24:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm date of COVID-19 test, which is reported as 06 NOV but case narrative reflects subject was tested on 05 NOV and received positive results on 07 NOV.' answered with 'Date of test is 05 Nov 2020. Subject was notified on 07 Nov 2020 but test states it was reported on 06 Nov 2020' (Site from Safety).	Emily Crews (b) (4)	29 Dec 2020 00:22:11
User opened query 'PV Query: Please confirm date of COVID-19 test, which is reported as 06 NOV but case narrative reflects subject was tested on 05 NOV and received positive results on 07 NOV.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:46:21
User opened query 'PV Query: Please confirm date for Day 7 in the COVID-19 assessment log. Currently is reported as 19 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:45:44
User opened query 'PV Query: Please provide the details of the positive test result of COVID-19 on 05 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:45:07
User entered 'Both per subject report and external lab records, subject has positive Covid 19 infection.'	Ruba Zanaid (b) (4)	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:05:47
User entered '0'	System	08 Dec 2020 22:18:48

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 23:48:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:48:34
Data point term sent to Coder	System	04 Jan 2021 23:48:08
User entered 'Sinusitis'	Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '04 Nov 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
User entered empty.	System	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '09 Nov 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
User entered empty.	System	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'None (NONE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'l'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:16:03
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
User entered '0'	System	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19
User entered '1'	System	04 Jan 2021 23:47:25

US3772037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:46:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:46:19

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:46:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:40:51
User closed query 'Per CDM: Response noted. Please document prior Facial Injections on the Medical History or Prior/Concomitant Medication and Vaccination page. Thank you.	(b) (4), (b) (6)	05 Apr 2021 17:10:05
' (Site from DM). Query 'Per CDM: Response noted. Please document prior Facial Injections on the Medical History or Prior/Concomitant Medication and Vaccination page. Thank you.	Emily Crews (b) (4) (b) (4)	02 Apr 2021 16:24:13
' answered with 'Added to MedHx' (Site from DM). User opened query 'Per CDM: Response noted. Please document prior Facial Injections on the Medical History or Prior/Concomitant Medication and Vaccination page. Thank you.	(b) (4), (b) (6)	30 Mar 2021 15:54:13
' (Site from DM). User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:54:13

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'This injection was given prior to start of study. Another CRC tried to enter this data and was auto queried that it was given prior to ICF date and shouldn't be documented please clarify where we should document prior Facial Injections' (Site from DM).	Emily Crews (b) (4) (b) (4)	23 Mar 2021 16:49:00
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:40:27
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:40:20
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:48:20
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1 Pain at Injection Site and Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:57:00

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:46:50

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 1 Pain at Emily Crews (b) (4) Injection Site and Headache (General) = Any use of (b) (4) prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject reported use of medication for pain at injection site when contacted regarding their use of medication recorded' (Site from DM).		02 Feb 2021 18:16:10
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1 Pain at Injection Site and Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:39:22
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:24:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:09:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:09:54
Data point term sent to Coder	System	11 Aug 2020 17:26:10
User entered 'Potassium chloride'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Kypokalemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '20'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'meq'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'twice daily (BID)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:56:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:25:51
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:25:51

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
Data point term sent to Coder	System	11 Aug 2020 17:27:13
User entered 'Rosuvastatin'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Hyperlipidemia'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '20'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:26:27
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:26:27

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:28:11
Data point term sent to Coder	System	11 Aug 2020 17:27:14
User entered 'Amlodipine'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Hypertension'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '5'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:27:05
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User entered '1'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User entered '1'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:04
User entered '804 (804)'	System	11 Aug 2020 17:27:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:29:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:29:13
Data point term sent to Coder	System	11 Aug 2020 17:28:14
User entered 'Levothyroxine'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Hypothyroidism'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '25'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'ug (ug)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:27:47
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User entered '1'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User entered '1'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:09
User entered '804 (804)'	System	11 Aug 2020 17:27:47

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:51
Data point term sent to Coder Coding entries removed.	System Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:10 06 Oct 2020 23:01:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:30:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:30:11
Data point term sent to Coder User entered 'Gabapentin'	System Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:16 11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:41
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:02
User entered 'NEUROPATHY (Right Ankle)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:01:55
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:02:47
User entered 'Neuropathy'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '100'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'twice daily (BID)' reason for change:	Emily Crews (b) (4)	11 Aug 2020 17:31:12
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:29:05
User entered 'un UNK 2014'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User entered '2'	System	11 Aug 2020 17:31:12
User entered '1'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User entered '1'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:59:15
User entered '804 (804)'	System	11 Aug 2020 17:29:05

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:31:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:31:12
Data point term sent to Coder	System	11 Aug 2020 17:30:17
User entered 'Hydrochlorothiazide'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Hypertension'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '25'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:29:43
User entered 'un UNK 2010'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:29:43

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:32:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:32:15
Data point term sent to Coder	System	11 Aug 2020 17:31:18
User entered 'Symbicort'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Asthma'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '160/4.5'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:31
User entered 'ug (ug)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:02:25
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:03:06
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'twice daily (BID)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 17:57:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 17:30:48
User entered 'un UNK 2015'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 17:30:48

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
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)	14 Aug 2020 15:46:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:46:23
Data point term sent to Coder User entered 'Tylenol'	System Emily Crews (b) (4) (b) (4)	14 Aug 2020 15:45:02 14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4) (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:06:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:03:08

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:03:27
User entered 'Pain at injection site'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4)	
	Emily Crews (b) (4)	14 Aug 2020 15:43:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29
	(b) (4)	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '500'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once (ONCE)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '13 Aug 2020'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '13 Aug 2020'	Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4)	06 Oct 2020 23:02:39
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	(b) (4) Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4) (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:16
User entered empty.	System	14 Aug 2020 15:44:13
DataPoint activated with code reason code Data required.	Emily Crews (b) (4)	14 Aug 2020 15:43:32
DataPoint inactivated with code reason code Data not required.	Emily Crews (b) (4)	11 Aug 2020 17:31:29

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
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)	23 Nov 2020 22:20:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:20:59
Data point term sent to Coder	System	23 Nov 2020 22:19:33
User entered 'Influenza Vaccination'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Influenza Prophylaxis'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0.5'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mL (mL)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '27 Oct 2020'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '27 Oct 2020'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:59
User entered empty.	System	23 Nov 2020 22:18:55

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:41:23
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
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: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 11:59:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 11:59:51
Data point term sent to Coder	System	05 Feb 2021 18:10:13
DataPoint Un-verified.	Sarah Sandberg (b) (4)	05 Feb 2021 18:09:12
Coding entries removed.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Feb 2021 18:09:12
User entered 'DEXAMETHASONE (DECADRON) (6mg / 1.5mL)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 20:41:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 20:41:39
Data point term sent to Coder	System	24 Nov 2020 19:06:35
User entered 'Dexamethasone (Decadron)'	Emily Crews (b) (4)	24 Nov 2020 19:05:44
	(b) (4)	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:41:23
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per CDM Re-query: Dexamethasone (Decadron) is not a combination drug and therefore only one component is expected to be recorded in this field. Since site reports 'Route of Administration' is 'Intravenous', 'Frequency' as 'Once daily', and site response indicates 'Dose per Administration' is 6 mg per 1.5 mL, in order to satisfy previous query, please consider updating 'Name of Medication Field' to include the mg per mL otherwise known as concentration/strength, i.e. Dexamethasone (Decadron) 6 mg/ 1.5 mL, if appropriate, in addition to updating 'Dose per Administration' to 6, and 'Dose Unit' to 'mg' if appropriate, else clarify. Thank you.' (Site from DM). Query 'Per CDM Re-query: Dexamethasone (Decadron) is not a combination drug and therefore only one component is expected to be recorded in this field. Since site reports 'Route of Administration' is 'Intravenous', 'Frequency' as 'Once daily', and site response indicates 'Dose per Administration' is 6 mg per 1.5 mL, in order to satisfy previous query, please consider updating 'Name of Medication Field' to include the mg per mL otherwise known as concentration/strength, i.e. Dexamethasone (Decadron) 6 mg/ 1.5 mL, if appropriate, in addition to updating 'Dose per Administration' to 6, and 'Dose Unit' to 'mg' if appropriate, else clarify. Thank you.' answered with 'Please review how this was updated and let me know if this is sufficient.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Sarah Sandberg (b) (4) (b) (4) Sarah Sandberg (b) (4) (b) (4)	08 Feb 2021 13:16:27 05 Feb 2021 18:09:19 05 Feb 2021 18:09:12
User entered '6' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	05 Feb 2021 18:09:12

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Dexamethasone (Decadron) is not a combination drug and therefore only one component is expected to be recorded in this field. Since site reports 'Route of Administration' is 'Intravenous', 'Frequency' as 'Once daily', and site response indicates 'Dose per Administration' is 6 mg per 1.5 mL, in order to satisfy previous query, please consider updating 'Name of Medication Field' to include the mg per mL otherwise known as concentration/strength, i.e. Dexamethasone (Decadron) 6 mg/ 1.5 mL, if appropriate, in addition to updating 'Dose per Administration' to 6, and 'Dose Unit' to 'mg' if appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:47:42
Query 'Per CDM Re-query: Decadron is not a combination drug and therefore only one component is expected to be recorded in this field. Since site reports 'Route of administration' is 'Intravenous', and site response indicates 'Dose per administration' is the expected 6 mg, please consider updating 'Dose per Administration' to 6, and 'Dose Unit' to 'mg' if appropriate, else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:48:52
User opened query 'Per CDM Re-query: Decadron is not a combination drug and therefore only one component is expected to be recorded in this field. Since site reports 'Route of administration' is 'Intravenous', and site response indicates 'Dose per administration' is the expected 6 mg, please consider updating 'Dose per Administration' to 6, and 'Dose Unit' to 'mg' if appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:05:03
User closed query 'Per DM CLR: Please note, 6/1.5 mg/ml is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 6 mg, etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:05:03

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, 6/1.5 mg/ml is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 6 mg, etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' answered with 'This is the information that was provided on medical records. this is the only documentation that can be provided' (Site from DM).	Emily Crews (b) (4) (b) (4)	02 Feb 2021 17:53:00
User opened query 'Per DM CLR: Please note, 6/1.5 mg/ml is a concentration/strength, rather than dosage. Please update the Con Med entry to list the specific dose and unit [e.g. 6 mg, etc.] within the DOSE and UNIT fields and provide the concentration/strength in the Name of Medication field. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:51:54
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 0.5/3 mg, etc) instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:51:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 0.5/3 mg, etc) instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:51:44
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '6/1.5'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:41:23
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4) Sarah Sandberg (b) (4)	05 Feb 2021 18:09:12
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Sarah Sandberg (b) (4)	05 Feb 2021 18:09:12
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:41:23
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Un-verified.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Feb 2021 18:09:12
User entered empty; reason for change Data Entry Error	(b) (4)	05 Feb 2021 18:09:12
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg/mL'	Emily Crews (b) (4)	24 Nov 2020 19:05:44
	(b) (4)	

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Intravenous (INTRAVENOUS)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '12 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User entered '1'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User entered '1'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:48
User entered '804 (804)'	System	24 Nov 2020 19:05:44

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:35:06
Data point term sent to Coder	System	23 Nov 2020 22:33:53
User entered 'Cefdinir'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
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) (4), (b) (6)	06 Jan 2021 07:42:20
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 'AE added' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:47:51
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)	02 Jan 2021 18:57:18
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Sinusitis'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '300'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '07 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User entered '2'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User entered '1'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:28
User entered '804 (804)'	System	23 Nov 2020 22:33:07

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:19:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:19:14
Data point term sent to Coder	System	23 Nov 2020 22:41:07
User entered 'Advil'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
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)	08 Feb 2021 13:18:08
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 'Subject has an AE for sinusitis with corresponding dates' (Site from DM).	Emily Crews (b) (4)	02 Feb 2021 18:13:19
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)	29 Jan 2021 02:48:36
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Sinusitis'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '200'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '05 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User entered '2'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User entered '1'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:22
User entered '804 (804)'	System	23 Nov 2020 22:40:30

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:20:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:20:00
Data point term sent to Coder	System	24 Nov 2020 19:18:52
User entered 'Dexamethasone'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 13:19:06
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'Will updated AE' (Site from DM).	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:13:38
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:51:05
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '6'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg (mg)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once daily (QD)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Oral (ORAL)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '13 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '16 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User entered '1'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User entered '1'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:36
User entered '804 (804)'	System	24 Nov 2020 19:18:15

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:32:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:32:22
Data point term sent to Coder	System	24 Nov 2020 19:19:53
User entered 'Supplemental Oxygen'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'I'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Liter'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Continuous'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Nasal (NASAL)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '08 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '10 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:58:08
User entered empty.	System	24 Nov 2020 19:19:01

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:19:09
Data point term sent to Coder	System	24 Nov 2020 19:20:55
User entered 'DuoNeb treatment (Ipratropium Bromide/ Albuterol Sulfate)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'COVID-19'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 0.5/3 mg, etc) instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 13:20:22
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 0.5/3 mg, etc) instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate. ' answered with 'This is the information that was provided n medical records' (Site from DM).	Emily Crews (b) (4) (b) (4)	02 Feb 2021 18:14:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 0.5/3 mg, etc) instead of dosage strength/concentration. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:51:36
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0.5/3/3'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Other (OTHER)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'mg/mg/mL'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'once (ONCE)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered empty.	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '0'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered '07 Nov 2020'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:55:49
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:46:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:57:53
User entered empty.	System	24 Nov 2020 19:20:16

US3772037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:46:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 05:41:32
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'No (N)'	(b) (4) Emily Crews (b) (4)	19 Feb 2021 17:17:10

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered	System	10 Nov 2020 15:42:05
'USA-US107-2020-MRNA-1273-P301000002'		

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered '10/Nov/2020 10:42'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered '17/Nov/2020 19:07'	System	17 Nov 2020 19:07:25

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 19:07:25

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered '19/Nov/2020 11:10'	System	19 Nov 2020 16:10:42

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:34:27
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 16:10:42

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered '25/Nov/2020 16:34'	System	25 Nov 2020 16:34:36

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 12:39:24
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 16:34:36

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered	System	10 Nov 2020 15:42:05
'USA-US107-2020-MRNA-1273-P301000002'		

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered '09/Dec/2020 07:39'	System	09 Dec 2020 12:39:35

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 17:28:42
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 02:53:56
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 12:39:35

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered	System	10 Nov 2020 15:42:05
'USA-US107-2020-MRNA-1273-P301000002'		

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '30/Dec/2020 12:28'	(b) (4) System	30 Dec 2020 17:28:59

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:00:13
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 17:28:59

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4)	16 Nov 2020 19:03:23
	(b) (4)	

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '26/Jan/2021 17:00'	(b) (4) System	26 Jan 2021 17:00:26

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:34
User entered '1'	(b) (4), (b) (6)	26 Jan 2021 17:00:26

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'USA-US107-2020-MRNA-1273-P301000002'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Yes (Y)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'No (N)'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Jamshid'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Saleh'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '3652 Eureka Way'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered 'Redding'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:19
Un-reviewed for Safety.	System	17 Nov 2020 19:07:25
User entered empty.	System	17 Nov 2020 19:07:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'California'	Emily Crews (b) (4) (b) (4)	16 Nov 2020 19:03:23

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:42:35
User entered '96001'	System	10 Nov 2020 15:42:05

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 02:53:56
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:07:14
User entered 'US'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
	(b) (4)	
User entered '8'	System	24 Feb 2021 18:42:50
User entered '7'	System	26 Jan 2021 17:00:26
User entered '6'	System	30 Dec 2020 17:28:59
User entered '5'	System	09 Dec 2020 12:39:35
User entered '4'	System	25 Nov 2020 16:34:36
User entered '3'	System	19 Nov 2020 16:10:42
User entered '2'	System	17 Nov 2020 19:07:25
User entered '1'	System	10 Nov 2020 15:42:46

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:46:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered '24/Feb/2021 13:42'	(b) (4) System	24 Feb 2021 18:42:50

US3772037

Folder: SAE USA-US107-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:15:44
User signature succeeded.	Jamshid Saleh (b) (4)	26 Feb 2021 05:10:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:42:50